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14. ABSTRACT:

Increasingly, the cultural beliefs and values of women are being recognized as important factors in genetic counseling for breast cancer susceptibility. Despite recommendations to increase the cultural sensitivity of genetic counseling, such programs have not been developed or evaluated. The objectives of this study are to develop a Culturally Tailored Genetic (CTGC) protocol for African American women and evaluate its impact on decision-making and satisfaction about BRCA1/2 testing, quality of life, and cancer control practices. A secondary objective of this study is to identify African American women who are most and least likely to benefit from CTGC vs. SGC. The key research accomplishments achieved during the past year include continuing an active program of subject recruitment, completing genetic counseling and education, and generating peer-reviewed manuscripts. The results generated during the past year demonstrate that while rates of test result acceptance may be low among African American women, the majority of women are extremely satisfied with genetic counseling. Satisfaction with culturally tailored genetic counseling may be especially high among some African American women at increased risk for hereditary disease.

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A. INTRODUCTION

Five to 10% of all breast cancer cases have been attributed to two breast-ovarian cancer susceptibility genes called BRCA1 and BRCA2 (BRCA1/2). Genetic counseling and testing for BRCA1/2 mutations is now available through clinical research programs using standard counseling protocols. The goal of pre-test counseling is to facilitate informed decision making about whether to be tested and to prepare participants for possible outcomes. The goal of post-test counseling is to provide information about risk status, recommendations for surveillance, and options for prevention. However, previous research suggests that African American and Caucasian women differ in their attitudes about and responses to pre-test education and counseling (Hughes et al., 1997; Lerman et al., 1999). Increasingly, cultural beliefs and values are being recognized as important factors in genetic counseling. Despite recommendations to increase the cultural sensitivity of breast cancer risk counseling, such programs have not been developed or evaluated. Therefore, the purpose of this study is to develop a Culturally Tailored Genetic Counseling (CTGC) protocol for African American women and evaluate its impact on psychological functioning and health behaviors compared with Standard Genetic Counseling (SGC) in a randomized clinical trial. This research is linked with Dr. Hughes' Career Development Award and has the following primary technical objectives:

(1) To evaluate the relative impact of CTGC vs. SGC on decision-making and satisfaction about BRCA1/2 testing. Compared to SGC, CTGC will lead to higher rates of test acceptance and satisfaction with testing decisions. These effects will be mediated by increases in perceived benefits and decreases in perceived limitations and risks of genetic testing.

(2) To evaluate the impact of CTGC vs. SGC on quality of life and health behaviors following BRCA1/2 testing. Compared to SGC, CTGC will lead to larger decreases in general and cancer-specific distress, greater increases in adherence to cancer screening guidelines, and lower rates of prophylactic surgery. Reductions in psychological distress will be mediated by increased use of spiritual coping strategies.

Secondary Aim

To identify African American women who are most and least likely to benefit from CTGC vs. SGC. We predict that the relative benefits of CTGC will be greatest for women with greater endorsement of African American cultural values and those identified as BRCA1/2 carriers.

B. BODY

The research was transferred to the University of Pennsylvania Medical Center in February 2002 and approval for the use of human subjects was granted in February 2003. The fourth year of the study focused on (1) continuing subject recruitment, (2) completing genetic counseling and education sessions, and (3) generating peer-reviewed manuscripts. These activities are described in detail in the sections 1 through 3 below. Manuscripts that have been generated with grant support are described in section 3. This project is linked with Dr. Hughes' Career Development Award (CDA) and activities regarding professional development are described in section 4.

Summary of Accomplishments During the Past Year

(1) Subject Recruitment. Eligible subjects are African American women ages 18 and older who have a 5%-10% prior probability of having a BRCA1/2 mutation based on their personal and family history of breast and/or ovarian cancer. Eligible subjects are identified by referrals from mammography and oncology clinics located at the University of Pennsylvania and through the community-based referral network that was developed specifically for the study. Following referral, eligible women are mailed an invitation letter that includes information about the purpose of the study and a reply card for women to return if they are not interested in participating. Women who do not return a reply card declining study participation are contacted by telephone to complete a structured baseline telephone interview. This interview takes approximately forty minutes to complete and includes measures of sociodemographic characteristics, personal and family history of cancer, perceived risk of having a BRCA1/2 gene alteration, and psychological functioning. Following completion of the baseline telephone interview, eligible subjects are invited to participate in pre-test education and counseling. Those who agree to participate in this session are randomly assigned to receive Standard Genetic Counseling (SGC) or Culturally Tailored Genetic Counseling (CTCG). Written informed consent is obtained for participation in pre-test education and counseling. After completion of the pre-test education session, subjects who are interested in genetic testing for BRCA1/2 mutations are given an opportunity to consider their decision further and have an opportunity to meet individually with a medical oncologist. Following the meeting with the medical oncologist, blood is drawn for genetic testing after obtaining written informed consent. Once BRCA1/2 test results are available, test results are disclosed using the protocol that is consistent with the format used to provide pre-test education and counseling (SGC or CTCG).

Accrual and Response Rates. To date, a total of 330 eligible subjects have been identified and of these, 198 (60%) completed the baseline telephone interview and agreed to participate in the study, 66 (20%) declined to participate in the study, 60 (18%) could not be reached after multiple attempts, and 6 (2%) are pending contact.

(2) Genetic Counseling and Education. Of the 198 eligible women who have enrolled in the study, 104 (53%) agreed to participate in pre-test education and counseling and 94(47%) declined to participate in pre-test education and counseling. Of the 104 women who agreed to participate in pre-test education and counseling, 49 (47%) have been randomized to SGC and 55 (53%) have been randomized to CTGC. A total of 102 pre-test education and counseling sessions have been completed, 93 women declined pre-test education and counseling, and 2 women are pending completion of pre-test education and counseling.

(3) Manuscripts.

Breast Cancer Screening Behaviors among African American Women with a Strong Family History of Breast Cancer (Halbert CH, Kessler L, Wileyto EP, Weathers B, Stopfer J, Domchek S, Collier A, Brewster K, Preventive Medicine, In press). Despite the importance of breast cancer screening to reduce morbidity and mortality, limited information is available on screening practices among African American women with a family history that is suggestive of hereditary breast cancer. The purpose of this study was to describe adherence to breast cancer screening

recommendations among African American women with a family history that is suggestive of hereditary disease. Participants were unaffected African American women (n=65) who had a family history of cancer that was suggestive of hereditary breast cancer. Breast cancer screening practices (e.g., mammography, clinical breast examination, and breast self-exams) were evaluated by self-report. Most women were adherent to recommendations for mammography (75%) and clinical breast examination (93%). However, a sizeable minority of women (41%) also performed excessive breast self-exam. Being older than age 50 was associated significantly with mammography adherence (Fisher's Exact Test < 0.05). Employment had a significant independent association with breast self-exam; unemployed women were most likely to perform excessive breast self-exam (OR=3.28, 95% CI: 1.05, 10.21, $p < 0.05$). The results of this study suggest a complex pattern of breast cancer screening practices among African American women at increased risk for hereditary breast cancer. Cancer risk counseling may be one strategy for increasing adherence to some breast screening modalities among African American women at risk for hereditary breast cancer.

Low Rates of Acceptance of BRCA1 and BRCA2 Test Results among African American Women at Increased Risk for Hereditary Breast-Ovarian Cancer (Halbert CH, Kessler L, Stopfer JE, Domchek S, Wileyto EP, Genetics in Medicine, In press). Although prior reports have evaluated participation in genetic counseling among African American women at increased risk for hereditary breast-ovarian cancer (Halbert et al., 2005), limited information is available on acceptance of BRCA1/2 test results in this population. This study evaluated rates of BRCA1/2 test result acceptance in African American women at increased risk for having a BRCA1/2 mutation and identified determinants of test result acceptance. Participants were 157 African American women at high and moderate risk for having a BRCA1/2 mutation. Overall, 22% of women who enrolled in the study received BRCA1/2 test results. Test result acceptance differed between women with a ≥10% prior probability of having a BRCA1/2 mutation (34%) and those who had a 5% prior probability (8%). Among women with a ≥10% prior probability, test result acceptors were most likely to be married (OR=5.29, 95% CI=1.82, 15.38, p=.002) and to be less certain about their risk of developing cancer (OR=3.18, 95% CI=1.04, 9.80, p=.04). These results demonstrate that acceptance of BRCA1/2 test results may be limited among African American women. Being married and having less certainty about one's cancer risk may motivate acceptance of BRCA1/2 test results among African American women. Our findings suggest that it may be important to emphasize the possibility that BRCA1/2 test results may not clarify cancer risks during pre-test counseling with African American women to ensure informed decision-making about testing.

Satisfaction with Genetic Counseling for BRCA1 and BRCA2 Mutations in African American Women (Charles S, Kessler L, Stopfer JE, Domchek S, Halbert CH, Patient Education and Counseling, In press). Although efforts are being made to increase African American participation in genetic counseling for hereditary breast cancer risk, limited information is available on satisfaction with these programs in these women. The objective of this study was to evaluate satisfaction with genetic counseling for BRCA1/2 mutations among African American women. Participants were 54 African American women at moderate and high risk for BRCA1/2 mutations who were offered genetic counseling as part of a randomized clinical trial designed to compare the effects of culturally tailored genetic counseling (CTGC) and standard genetic counseling (SGC). Satisfaction with genetic counseling was evaluated using a self-administered

questionnaire following culturally tailored or standard pre-test education and counseling. Overall, the majority of women (96%) were very satisfied with genetic counseling; however, only 26% reported that their worries were lessened and 22% reported that they were able to cope better. Women who received CTGC were significantly more likely than women who received SGC to report that their worries were lessened ($p < 0.05$). In addition, women with household incomes less than $35,000 were significantly more likely to report that the counselor lessened their worries compared to women with higher incomes ($p < 0.05$). These results demonstrate that most African American women may be satisfied with genetic counseling; however, women who received culturally tailored genetic counseling may be most likely to be satisfied with some aspects of counseling. Discussion of cultural beliefs and values during genetic counseling may be beneficial to African American women, especially those with low incomes.

Career Development Activities. Because this project is linked with Dr. Hughes' career development award, a summary of the professional development activities that were completed during the past year is included in this report. During the past year, Dr. Hughes has continued to be an integral member of the Abramson Cancer Center at the University of Pennsylvania. The program of research that Dr. Hughes has established with the support of the Breast Cancer Research Program has enabled her to assume leadership roles in several national committees that include being a member of the American Association for Cancer Research Behavioral Science Task Force and the Chair of the Community Assessment and Intervention Working Group for the Centers for Population Health and Health Disparities funded by the NIH. Dr. Hughes also serves on an NIH study section and has delivered four invited presentations during the past year.

C. KEY RESEARCH ACCOMPLISHMENTS

During the past year, our efforts have focused on continuing subject recruitment, completing genetic counseling and education, and generating peer-reviewed manuscripts. A summary of these accomplishments is described below.

- Continued to increase the number of eligible women identified for study participation. During the past year, a total of 102 eligible women were identified for study participation.
- Substantially increased the number of women enrolled in the study (114 women enrolled in the study during the past year, bringing the total number of study participants to 198).
- Doubled the number of genetic counseling and education sessions completed (51 pre-test education and counseling sessions were completed during the past year).
- Published 5 peer-reviewed manuscripts during the past year (to date, a total of 12 peer-reviewed papers have been published as a result of grant support).

D. REPORTABLE OUTCOMES

Manuscripts Published with Grant Support During the Past Year (Dr. Hughes now publishes using Chanita Hughes Halbert, Ph.D.)

Halbert CH, Kessler L, Collier A, Wileyto EP, Brewster K, Weathers B. Psychological functioning in African American women at increased risk for hereditary breast and ovarian cancer. *Clin Genet* 2005;68:222-227.

Halbert CH, Brewster K, Collier A, Smith C, Kessler L, Weathers B, Stopfer JE, Domchek S, Wileyto EP. Recruiting African American women to participate in hereditary breast cancer research. *J Clin Oncol* 2005;23:7967-7973.

Satia JA, McRitchie S, Kupper L, Halbert CH. Genetic testing for colon cancer among African Americans in North Carolina. *Prev Med* 2006;43:51-59.

Charles S, Kessler L, Stopfer JE, Domchek S, Halbert CH. Satisfaction with genetic counseling for BRCA1 and BRCA2 mutations among African American women." *Patient Educ Couns*. In press.

Halbert CH, Kessler L, Wileyto EP, Weathers B, Stopfer J, Domchek S, Collier A, Brewster K. Breast cancer screening behaviors among African American women with a strong family history of breast cancer. *Prev Med*. In press.

Halbert CH, Kessler L, Stopfer JE, Domchek S, Wileyto EP. Low rates of acceptance of BRCA1 and BRCA2 test results among African American women at increased risk for hereditary breast-ovarian cancer. *Genet Med*. In press.

Kessler L, Collier A, Halbert CH. Knowledge about Genetics among African Americans. *J Genet Couns.* In press.

Manuscripts Under Review and in Preparation

Brewster K, Wileyto EP, Kessler L, Collier A, Weathers B, Stopfer JE, Domchek S, Halbert CH. Sociocultural Predictors of Breast Cancer Risk Perceptions in African American Breast Cancer Survivors. Manuscript Under Review.

Weathers B, Brewster K, Collier A, Kessler L, Wileyto EP, Halbert CH. Religious Coping Efforts among African American Women at Increased Risk for BRCA1 and BRCA2 Mutations. Manuscript under Review.

Halbert CH, Schmitz K, Weathers B, Domchek S, Kessler L. Body Mass Index in African American Women at Risk for Breast Cancer. Manuscript Under Review.

Kessler L, Domchek S, Stopfer J, Halbert CH. BRCA1 and BRCA2 risk perceptions among African American Women at Increased Risk for Hereditary Breast-Ovarian Cancer. Manuscript Under Review.

Halbert CH, Kessler L, Collier A, Brewster K, Weathers B. Effects of Genetic Counseling for BRCA1 and BRCA2 Mutations in African American Women. Manuscript in Preparation.

Halbert CH, Collier A, Kessler L, Weathers B, Stopfer J, Domchek. Retaining African American Women in Cancer Genetics Research. Manuscript in Preparation.

Invited Lectures and Presentations Delivered with Grant Support

"Satisfaction with Genetic Counseling for BRCA1 and BRCA2 Mutations among African American Women." Paper presented at the National Society of Genetic Counselors Annual Education Conference, Los Angeles, CA, 2005.

"Utilization of Religious Coping Strategies among African American Women at Increased Risk for Hereditary Breast and Ovarian Cancer." Poster presented at the Cancer, Culture, and Literacy: Solutions for Addressing Health Disparities through Community Partnerships Conference, Clearwater Beach, FL, 2006.

"Psychological Functioning in African American Women at Increased Risk for Hereditary Breast-Ovarian Cancer,"Center for Eliminating Health Disparities, School of Public Health, St. Louis University, St. Louis, MO (Invited Lecture)

"Genetic Counseling and Testing for BRCA1 and BRCA2 Mutations in African American Women," The Robert Wood Johnson Foundation, Princeton, NJ (Invited Lecture)

"Culturally Tailored Genetic Counseling for BRCA1 and BRCA2 Mutations in African American Women,"Northwestern University, Chicago, IL (Invited Lecture)

"Genetic Counseling for Hereditary Breast Cancer Risk in African American Women," The University of Texas M.D. Anderson Cancer Center, Houston, TX (Invited Lecture)

E. CONCLUSIONS AND FUTURE PLANS

During the past year, our activities have focused on continuing subject recruitment, completing genetic counseling and education sessions, and generating peer-reviewed manuscripts. The past year of the study has been extremely productive and we have achieved a number of significant accomplishments. First, we have continued to demonstrate that it is possible to enroll African American women into hereditary breast cancer research. African American women have been under-represented in hereditary breast cancer research; however, we have been able to identify an additional 114 African American women at increased risk for hereditary disease and enroll these women into the study. This brings the total number of women enrolled in the study to 198. We have also been the first to evaluate several important outcomes of genetic counseling among African American women. Specifically, our evaluation of test result acceptance extends prior research on participation in genetic counseling (Halbert et al., 2005) and demonstrates that many African American women may decline genetic testing or BRCA1/2 test results. Nonetheless, the majority of women are satisfied with genetic counseling. These findings suggest that even if women decide to not have testing or receive results, participation in counseling, especially counseling that is sensitive to cultural beliefs and values, may be beneficial to African American women. During the next year of the project, we will continue to accrue subjects and perform

data analysis to address our study aims. These results will be presented at scientific conferences and prepared for publication.

F. REFERENCES

Halbert CH, Brewster K, Collier A, Smith C, Kessler L, Weathers B, Stopfer JE, Domchek S, Wileyto EP. Recruiting African American women to participate in hereditary breast cancer research. *J Clin Oncol* 2005;23:7967-7973.

Hughes C, Caminero AG, Benkendorf J, et al. Ethnic differences in knowledge and attitudes about BRCA1 testing in women at increased risk. *Patient Educ Couns* 1997;32:51-62.

Lerman C, Hughes C, Benkendorf JL, et al. Racial differences in testing motivation and psychological distress following pre-test education for BRCA1 gene testing. *Cancer Epidemiol Biomarkers Prev* 1999;8:361-367.

G. APPENDICES

See attached for published manuscripts generated with grant support.

DAMD17-00-1-0262

GENETIC COUNSELING FOR BREAST CANCER SUSCEPTIBILITY IN AFRICAN AMERICAN WOMEN

- Manuscripts published with grant support during the past year

IN PRESS – GENETICS IN MEDICINE

Original Research

Low Rates of Acceptance of *BRCA1* and *BRCA2* Test Results among African American Women at Increased Risk for Hereditary Breast-Ovarian Cancer

RUNNING TITLE: African American Test Result Acceptance

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IN PRESS – GENETICS IN MEDICINE

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IN PRESS – GENETICS IN MEDICINE

ABSTRACT

Purpose: This study evaluated rates of *BRCA1* and *BRCA2* (*BRCA1/2)* test result acceptance among African American women and identified determinants of test result acceptance.

Methods: Acceptance of *BRCA1/2* test results was evaluated among 157 African American women at high and moderate risk for having a *BRCA1/2* mutation who were offered genetic testing as part of a clinical genetic counseling research program.

Results: Twenty-two percent of women received *BRCA1/2* test results. Test result acceptance differed between women with a ≥10% prior probability of having a *BRCA1/2* mutation (34%) and those who had a 5% prior probability (8%). Among women with a ≥10% prior probability, test result acceptors were most likely to be married (OR=5.29, 95% CI=1.82, 15.38, p=.002) and be less certain about their risk of developing cancer (OR=3.18, 95% CI=1.04, 9.80, p=.04).

Conclusion: These results demonstrate that acceptance of *BRCA1/2* test results may be limited among African American women. Being married and having less certainty about one's cancer risk may motivate acceptance of *BRCA1/2* test results among African American women. It may be important to emphasize the possibility that *BRCA1/2* test results may not clarify cancer risks during pre-test counseling with African American women to ensure informed decision-making about testing.

Key Words: African American, *BRCA1 and BRCA2*, Test Result, Acceptance

INTRODUCTION

Recently, epidemiological studies have shown that the prevalence of *BRCA1* and *BRCA2* (*BRCA1/2*) mutations ranges between 16% to 28% among African American women who have a personal and family history of breast and/or ovarian cancer suggestive of hereditary disease.[1-4] If found to carry a *BRCA1/2* mutation, women have an estimated 60% to 80% lifetime risk of developing breast cancer and a 10% to 45% lifetime risk of developing ovarian cancer.[5-7] Because of the excess rates of breast cancer mortality among African American women,[8, 9] participation in genetic counseling and testing may be beneficial to women at increased risk for hereditary cancer to increase knowledge about cancer risks and options for risk reduction. Efforts are now being made to enhance access to genetic counseling and testing for *BRCA1/2* mutations among African American women at increased risk for hereditary disease. Recent research has shown that as many as 50% of African American women may participate in genetic counseling for breast cancer susceptibility,[10] but little is known about rates of acceptance of *BRCA1/2* test results or determinants of test result acceptance.

To address this gap in our knowledge, we evaluated rates of *BRCA1/2* test result acceptance among African American women at increased risk for hereditary breast and ovarian cancer and identified sociodemographic, clinical, and psychological barriers and facilitators to receiving genetic test results. Because prior studies have shown that cancer-specific worry may influence decisions about participating in genetic counseling among African American women[11] we were interested in exploring the relationship between *BRCA1/2* test result acceptance and cancer-specific worry. Other reports have shown that many African American women would want to have genetic testing to be reassured about their cancer risk;[12] however, it is possible that women who are uncertain about their risk of developing cancer may be most likely to receive test

results to better define their risk of disease. Thus, we were also interested in determining whether certainty about one's risk of developing breast cancer is associated with genetic test acceptance. Since previous research has shown that responses to education about hereditary breast cancer and genetic testing may differ among African American women depending on the extent to which information addresses individual concerns,[11] a secondary aim of the study was to explore whether two forms of pre-test counseling, culturally tailored versus standard, influence acceptance of *BRCA1/2* test results among women who participate in pre-test counseling. Information on rates and determinants of *BRCA1/2* test result acceptance will provide important information on uptake of this service among African American women at increased risk for hereditary breast and ovarian cancer.

MATERIALS AND METHODS

Study Population

Participants were African American women (n=157) at increased risk for having a *BRCA1/2* mutation. To be eligible for participation, women had to self-identify as being African American or Black and have at least a 5% to 10% prior probability of having a *BRCA1/2* mutation based on their personal and family history of breast and/or ovarian cancer. Prior probability of having a *BRCA1/2* mutation was estimated based on the participant's personal and family history of breast and/or ovarian cancer using risk estimation models and empiric data from prior reports.[3, 13-15] The study was approved by the Institutional Review Board at the University of Pennsylvania.

Procedures

Women were recruited into the study though a referral network that included seven clinical institutions and community oncology resources located in Philadelphia, PA. At the clinical referral sites, brochures and flyers that contained information about the study were given to all African American women by physicians and clinic staff. Study brochures and flyers were given to women by research staff at community oncology resources. Women interested in learning more about genetic counseling completed a referral form that collected information on race, address, birth date, and personal and family history of cancer. Eligibility was determined by the study genetic counselor following referral and eligible women were mailed an invitation letter that described the study purpose and procedures involved in participation. Some women (n=27) were referred from a separate epidemiological study that was designed to identify genetic risk factors for breast cancer in African American women and had provided a blood sample before enrolling in this study. However, these women did not receive genetic counseling for hereditary breast-ovarian cancer susceptibility and clinical genetic testing for *BRCA1/2* mutations was not performed. Further, referral from the epidemiological study was not associated with decisions about enrolling in this study.[10] Study enrollment included completion of a structured baseline telephone interview that took about 40-minutes to complete. Both study enrollment and the baseline were completed by a trained interviewer at Penn after obtaining verbal consent. Project staff who completed the study enrollment and the baseline telephone interview were African American. The baseline assessed sociodemographics, cancer-specific worry, and risk perception variables. The response rate for the baseline telephone interview and study enrollment was 61% (see Figure 1). At the end of the baseline, women were invited to participate in genetic counseling; those who agreed to participate in counseling were randomized

to culturally tailored or standard genetic counseling. Detailed information on these counseling protocols is provided below under "Genetic Counseling Protocols." Women were recruited into the study from February 2003 through October 2005.

Genetic Counseling Protocols

Standard Genetic Counseling (SGC). Following provision of written informed consent, women randomized to SGC received pre-test counseling about hereditary breast and ovarian cancer, the inheritance and prevalence of *BRCA1/2* susceptibility genes, the process of genetic testing for *BRCA1/2* mutations, and interpretation of genetic test results using a semi-structured protocol. Risk of having a *BRCA1/2* mutation was also provided to women along with information about cancer risks associated with *BRCA1/2* mutations and the potential benefits, limitations, and risks of genetic testing. Possible test result outcomes (e.g., positive, negative, or variant of unknown significance) were also reviewed. The SGC session lasted about 90 minutes. Similar protocols have been used to provide pre-test counseling in prior studies.[16, 17]

Culturally Tailored Genetic Counseling. The CTGC protocol provided the same education about hereditary cancer, genetic testing, and risk information as the SGC protocol after written informed consent was obtained. However, consistent with guidelines for providing culturally competent genetic counseling,[18, 19] the CTGC protocol included standardized probes to elicit discussion about cultural factors that have been shown to influence decisions about genetic counseling among African American women in prior reports (e.g., spiritual and religious beliefs, communalism).[20, 21] For example, women were asked what aspects of their spiritual and religious beliefs influence their decision to have genetic testing to facilitate discussion about the role of these factors in decision-making about genetic testing for *BRCA1/2* mutations. Women

were also asked questions such as how their familial experiences with breast and ovarian cancer influenced their decisions to have genetic testing to facilitate discussions about values related to communalism. The CTGC sessions lasted about 90 to 120 minutes. The study genetic counselor (LK) took detailed counseling notes after CTGC and SGC to document the issues discussed during pre-test counseling and these notes were reviewed by the PI (CHH) to ensure adherence to the counseling protocols. In addition, counseling sessions were randomly audio taped and reviewed by the PI to ensure adherence to the counseling protocols. The SGC and CTGC sessions were conducted using a semi-structured protocol that included visual aids to standardize the educational content and a written summary of the educational content was provided to women to refer to after the session. Sessions were conducted individuals by a board certified genetic counselor (LK) who was Caucasian.

At the end of culturally tailored or standard genetic counseling, women were given an opportunity to provide a blood sample for genetic testing. Women who were interested in having genetic testing were scheduled for a meeting with a medical oncologist (SD). During this visit, women discussed any new medical issues and were offered a clinical breast examination. Possible test result outcomes, as well as the risks and benefits of genetic testing, were reviewed by the medical oncologist. Specific issues that were discussed were the ways that knowledge of *BRCA1/2* mutation status might influence medical management (e.g., oophorectomy, enhanced screening) for themselves and their family members, as well as the possibility of variants of unknown significance. Blood samples were obtained from women who were interested in genetic testing following provision of written informed consent at the end of this appointment. When test results became available, women were contacted by telephone by the study genetic

counselor to schedule a test results disclosure session. Costs for genetic testing were paid by the participant's insurance company or by institutional funds at the Abramson Cancer Center.

Participants who provided a blood sample were invited to attend an individual test result disclosure and counseling session when their *BRCA1/2* test results became available. Following provision of written informed consent, *BRCA1/2* test results were disclosed by the genetic counselor and medical oncologist. Women were also provided with information about their risk of developing cancer, individualized guidelines for surveillance and prevention options, and risk of having a BRCA1/2 mutation among family members. Following disclosure of *BRCA1/2* test results and discussion of guidelines for cancer screening and surveillance, a semi-structured culturally tailored protocol was used to facilitate discussion of cultural belief and values that were addressed during the pre-test counseling session among women who were randomized to CTGC. For example, women were asked what aspects of their religious and spiritual beliefs would they use to cope with their *BRCA1/2* test results. Women were also asked which family members would they lean on for support following test results disclosure and how would they react if relatives did not want to know their *BRCA1/2* test results.

Regardless of test result and randomization to CTGC or SGC, all women received a written report that included an interpretation of their *BRCA1/2* test result and guidelines for medical management. In addition, all women were contacted by the study genetic counselor approximately two weeks following the test result disclosure session to answer any additional questions and to provide additional referrals, if needed.

Measures

Sociodemographics. Income, marital status, education, and employment status were obtained during the baseline telephone interview. Responses to these items were re-coded into dichotomous variables (e.g., not married vs. married) based on the distribution of responses.

Clinical factors. Age, personal history of cancer, and family history of disease were obtained by self-report. Women were categorized as being age 50 or younger or older than age 50. The total number of first-, second-, and third-degree relatives diagnosed with breast and/or ovarian cancer was calculated because it is standard practice to construct a three-generation pedigree for genetic counseling.[22] Women were categorized as having two or more affected relatives or less than two relatives affected with breast and/or ovarian cancer.

Psychological variables. Psychological factors were evaluated in terms of certainty about one's risk of developing cancer, perceived risk of having a *BRCA1/2* mutation, and cancer-specific worry. Specifically, we used one Likert-style item validated in previous research on genetic counseling for inherited breast cancer risk to evaluate perceived risk of having a *BRCA1/2* mutation.[11,23] Certainty about one's risk of developing cancer was evaluated with a Likert-style item that asked women how certain they were of their chances of getting breast cancer (1=not at all certain, 2=a little certain, 3=somewhat certain, 4=very certain). Similar types of items have been used in prior research to evaluate certainty about one's breast cancer risk.[24] Responses to these items were re-coded into dichotomous variables based on the distribution of responses (e.g., at risk *versus* not at risk and more certain *versus* less certain). We used the breast cancer worry scale to evaluate cancer-specific worry.[25] This questionnaire asked women to indicate

how much they thought about their chances of developing breast cancer and how much thoughts about developing breast cancer impacted their mood and ability to perform their daily activities. This scale has been used to measure cancer-specific worry among women seeking genetic counseling for *BRCA1/2* mutations in previous research[26] and had good internal consistency in this sample (Cronbach's alpha=.75).

Acceptance of *BRCA1/2* test results. Women were classified as either *BRCA1/2* test result acceptors or decliners. Acceptors included women who participated in genetic counseling, provided a blood sample for testing, and received *BRCA1/2* test results. As in prior reports,[16,27] decliners included women who did not receive *BRCA1/2* test results within 8 to 12 weeks of being notified that results were available, women who declined to participate in genetic counseling, and those who declined to provide a blood sample for testing following pre-test counseling. We compared women who declined to participate in genetic counseling to those who declined genetic testing or test results and there were no differences in terms of sociodemographic characteristics (e.g., marital status, Chi Square=0.19, p=0.66), clinical factors (e.g., cancer history, Chi Square=1.28, p=0.26), or psychological variables (e.g., breast cancer certainty, Chi Square=0.13, p=0.72). Costs for genetic testing were paid by institutional funds for women with a ≥10% prior probability of having a BRCA1/2 mutation. For women with a 5% prior probability, these costs were paid by insurance companies.

Data Analysis

We first generated frequencies to characterize participants in terms of sociodemographics, clinical factors, and acceptance of *BRCA1/2* test results. Next, we

conducted chi square analysis to evaluate the relationship between randomization to CTGC and SGC and sociodemographics and clinical factors. We then conducted chi square tests of association to evaluate the relationship between *BRCA1/2* test result acceptance and randomization to CTGC and SCG. We then conducted bivariate analyses to evaluate the relationship between *BRCA1/2* test result acceptance and sociodemographics, clinical factors, and cancer-specific worry using a combination of chi square tests of association for dichotomous variables and nonparametric analysis of variance for continuous measures. These analyses were stratified by *BRCA1/2* prior probability because of differences in coverage for genetic testing expenses among women with a ≥10% prior probability and those with a 5% prior probability. We then conducted multivariate logistic regression analysis to identify factors having independent associations with *BRCA1/2* test result acceptance. Variables that had a bivariate association of $p<.10$ with test result acceptance were included in the logistic regression model.

RESULTS

Sample Characteristics

As shown in Table 1, the sample consisted mostly of women who had a ≥10% prior probability of having *BRCA1/2* mutation (53%). In addition, most women were ages 50 and younger (61%), were not married (69%), had some college education or were college graduates (69%), were employed (62%), and had an annual household income less than $35,000 (52%). Ninety-seven percent of women had health insurance. There were no differences in sociodemographic characteristics between women who had a ≥10% prior probability of having a *BRCA1/2* mutation and those who had a 5% prior probability. Overall, 64% of women had a personal history of breast and/or ovarian cancer and most women had two or more relatives

affected with cancer (59%). In terms of randomization to genetic counseling, 48% of women were randomized to CTGC (n=65) and 52% were randomized to SGC (n=71). Women who did not participate in the prior epidemiological study (χ^2=6.95, p=.01) and those with a high school education or less (χ^2=6.22, p=.01) were more likely to be randomized to CTGC; however, there were no differences in marital status (χ^2=0.31, p=.72), income (χ^2=0.01, p=.93), employment (χ^2=1.06, p=0.30), cancer status (χ^2=0.14, p=.70), family history of cancer (χ^2=0.004, p=.95), or *BRCA1/2* prior probability (χ^2=0.96, p=.33) between women randomized to CTGC and SGC.

Acceptance of Genetic Test Results

There were no differences in *BRCA1/2* test result acceptance in the total sample of women who were randomized to CTGC and SGC (n=136) (22% versus 28%, χ^2=0.80, p=.37) or among women who participated in pre-test counseling. Among participants in pre-test counseling, 47% were test result acceptors and 53% declined. Since there were no differences in test result acceptance among women randomized to CTGC or SGC, we evaluated rates of test result acceptance in the total sample of women who enrolled in the study. Among all women (n=157), 22% were test result acceptors and 78% were decliners; however, test result acceptance was greater among women who had a ≥10% prior probability of having a *BRCA1/2* mutation (34%) compared to those who had a 5% prior probability (8%) (χ^2=15.14, p= 0.001). Of the women who received test results, 15% were mutation carriers, 65% were *BRCA1/2* negative, and 21% had variants of uncertain significance. Since a small number of women with a 5% prior probability received *BRCA1/2* test results (n=6), we did not complete analyses to identify factors associated with test result acceptance among these women; thus, the analysis presented below is based on women with a ≥10% prior probability who enrolled in the study (n=83).

Of the sociodemographic factors, only marital status was associated significantly with *BRCA1/2* test result acceptance. Women who were married were significantly more likely to receive *BRCA1/2* test results compared to those who were not married (χ^2=9.16, p=.002). In addition, cancer-specific worry was greater among women who received *BRCA1/2* test results compared to decliners (Kruskal-Wallis χ^2=2.87, p=.09). However, women who were less certain about their risk of developing cancer (42%) were more likely to receive *BRCA1/2* test results compared to women who were more certain about their risks (22%) (χ^2=3.51, p=.06). No other sociodemographic, clinical factors, or psychological variables were associated significantly with *BRCA1/2* test result acceptance.

Predictors of Test Result Acceptance

In the multivariate logistic regression model of acceptance of *BRCA1/2* test results, only marital status and certainty about breast cancer risk had significant independent associations with test result acceptance. As shown in Table 3, women who were married were about five times more likely than unmarried women to receive *BRCA1/2* test results (OR=5.29, 95% CI=1.82, 15.38, p=.002). In addition, women who were less certain about their cancer risk were about three times more likely to receive *BRCA1/2* test results compared to women who were more certain (OR=3.18, 95% CI=1.04, 9.80, p=.04). We re-ran the model controlling for education and participation in the prior epidemiological study and the results were unchanged (marital status, OR=5.84, 95% OR=1.92, 17.77, p=.002; certainty, OR=3.39, 95% CI=1.06, 10.82, p=.04).

DISCUSSION

Prior reports have evaluated participation in genetic counseling among African American women;[10, 20, 26] however, to our knowledge, this study is the first to document rates of actual *BRCA1/2* test result acceptance among African American women at increased risk for hereditary breast and ovarian cancer. Overall, 22% of women received *BRCA1/2* test results; once women underwent pre-test counseling, 47% of women received *BRCA1/2* test results. These findings suggest that acceptance of *BRCA1/2* test results may be limited among African American women at increased risk for hereditary cancer, especially in comparison to acceptance rates reported for other populations.[16,27] Importantly, however, acceptance rates did not differ between women who received culturally tailored and standard genetic counseling. Cultural beliefs and values are increasingly being recognized as important factors in genetic counseling[18, 19,28] and our recent study found that African American women who received culturally tailored genetic counseling were more satisfied with some aspects of counseling compared to those who received standard genetic counseling.[29] However, the effect of genetic counseling on *BRCA1/2* test result acceptance was based on a limited number of women who completed pre-test counseling; thus, this exploratory finding should be interpreted with caution.

The results of this study provide some insight into factors that are likely to motivate acceptance of *BRCA1/2* test results among African American women. We found that women who were less certain about their risk of developing breast cancer were about three times more likely to receive *BRCA1/2* test results compared to women who were more certain about their risks. Provision of risk information is a key component of genetic counseling for *BRCA1/2* mutations[20,31] and previous research has shown that obtaining information about cancer risks is an important motivation for genetic testing among African American women.[12] However, recent

research has shown that many African American women may have *BRCA1/2* variants of unknown significance;[4] thus, genetic testing may not clarify cancer risks for these women. This underscores the importance of preparing African American women for this possible outcome during pre-test counseling and ensuring that women understand the clinical implications of genetic test results as part of test results disclosure.

We also found that women who were married were most likely to receive *BRCA1/2* test results whereas cancer-specific worry did not have a significant effect on *BRCA1/2* test result acceptance. Previous research has demonstrated that guilt about passing a *BRCA1/2* mutation to relatives may be a barrier to participation in genetic counseling among African American women.[20] However, women are likely to discuss genetic testing with their partner before making a decision about testing.[32] It is possible that married women may have been encouraged to have testing by their spouses and/or partners (Hughes, unpublished data, 1997). Spouses are an important resource for emotional support following breast cancer diagnosis among African American women;[33] the availability of spousal and/or partner support following test results disclosure may have also motivated women to receive *BRCA1/2* test results. Thus, while cancer-specific worry may not be a barrier to *BRCA1/2* test result acceptance among African American women, lack of encouragement or support from spouses and/or partners may decrease acceptance of genetic test results.

In considering the results of this study, some limitations should be noted. First, rates of genetic test acceptance were based on 61% of eligible women who enrolled in the study. The challenges associated with recruiting African American women to participate in cancer research are well-documented;[34-37] however, the enrollment rates for the present study are similar to the rates reported in studies that evaluated genetic testing decisions in Caucasian samples.[27, 38] An

additional limitation is that we had limited statistical power to detect small differences in test result acceptance rates between women randomized to CTGC and SGC and the model predicting *BRCA1/2* test result acceptance was based only on women with a ≥10% prior probability of having a mutation. However, to our knowledge, our report includes the largest sample of African American women at increased risk for hereditary breast cancer to be enrolled in a prospective randomized trial and we had 80% power to detect moderate effects in the total sample of women randomized to CTGC and SGC and in the subset of women included in the model predicting test result acceptance. Nonetheless, additional research is needed to evaluate acceptance of *BRCA1/2* test results in larger samples of African American women. Since decliners included women who declined genetic counseling as well as those who declined testing or results, additional research may be needed to evaluate testing decisions based on more uniform groups of women who choose not to participate in genetic counseling, decline genetic testing, or elect to not receive results. However, women who declined genetic counseling did not differ from those who declined testing and/or results in terms of sociodemographic characteristics, clinical factors, or psychological variables. Previous research has shown that racial concordance with health care providers may be important for effective communication;[40] the lack of racial concordance between participants and the genetic counselor may explain the low rates of genetic test acceptance observed in this study. However, the majority of African American women were extremely satisfied with genetic counseling even though they were not racially concordant with the counselor.[29] Thus, we do not believe that racial discordance between the counselor and participants was a factor in decisions about genetic testing. However, this is an important area for future research.

Despite these potential limitations, the results of this study demonstrate that acceptance of *BRCA1/2* test results may be limited among African American women. Since lack of spousal/partner support may be a barrier to acceptance of *BRCA1/2* test results among African American women, it may be useful to identify other resources for support as women considering testing. Previous research has shown that individuals who have more cohesive relationships with family members are most likely to receive *BRCA1/2* test results.[38] Thus, other family members might be able to provide support to women who are not married as these individuals consider genetic testing for *BRCA1/2* mutations. Since African American women may be likely to receive *BRCA1/2* test results to clarify their risks of developing cancer, our results also underscore the importance of discussing possible testing outcomes and the likelihood that *BRCA1/2* test results may not clarify cancer risks as part of pre-test counseling with African American women to ensure that women make informed decisions about testing. Additional research is needed to understand the effects of *BRCA1/2* test results, especially uncertain risk information, on psychological functioning and cancer screening behaviors among African American women.

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Table 1. Sample Characteristics (n=157)

Variable	**Level**	**Total Sample (n=157) n (%)**	**≥10% *BRCA1/2* Prior Probability (n=83) n (%)**	**5% *BRCA1/2* Prior Probability (n=74) n (%)**	χ^2
Age	≤ 50	95 (61%)	54 (65%)	41 (55%)	1.52
	> 50	62 (39%)	29 (35%)	33 (45%)	
Marital status	Not married	109 (69%)	54 (65%)	55 (74%)	1.58
	Married	48 (31%)	29 (35%)	19 (26%)	
Education level	≥ Some college	109 (69%)	58 (70%)	51 (69%)	0.02
	≤ High school	48 (31%)	25 (30%)	23 (31%)	
Employment status	Employed	98 (62%)	48 (58%)	50 (68%)	1.58
	Not employed	59 (38%)	35 (42%)	24 (32%)	
Income level	< $35,000	82 (52%)	45 (54%)	37 (51%)	0.19
	> $35,000	74 (48%)	38 (46%)	36 (49%)	
Insurance status	Yes	152 (97%)	81 (98%)	71 (96%)	0.34
	No	5 (3%)	2 (2%)	3 (4%)	

Table 2. Multivariate Logistic Regression Model of BRCA1 and BRCA2 Test Result Acceptance[a]

Variable	Estimate	SE	OR (95% CI)
Marital status, Married/Not married	1.67	0.54	5.29 (1.82, 15.38)[b]
Risk certainty, Less certain/More certain	1.16	0.57	3.18 (1.04, 9.80)[c]
Breast cancer worries[d]	0.12	0.10	1.35 (0.83, 2.20)

[a]Only includes women with a ≥10% *BRCA1/2* prior probability; n=81 because of missing data.
[b]p=002; [c]p=.04
[d]Odds ratio reflects the increase in odds associated with 1 standard deviation increase in the continuous measure of breast cancer worries.

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ORIGINAL REPORT

Recruiting African American Women to Participate in Hereditary Breast Cancer Research

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ABSTRACT

Purpose
This study evaluated the process of recruiting African American women to participate in genetic counseling research for *BRCA1* and *BRCA2* (*BRCA1/2*) mutations with respect to referral, study enrollment, and participation in genetic counseling.

Patients and Methods
African American women (n = 783) were referred for study enrollment.

Results
Of 783 referrals, 164 (21%) women were eligible for enrollment. Eligible women were most likely to be referred from oncology clinics (44%) and were least likely to be referred from general medical practices (11%; χ^2 = 96.80; P = .0001). Overall, 62% of eligible women enrolled onto the study and 50% of enrollees completed genetic counseling. Women with a stronger family history of cancer (odds ratio [OR] = 3.18; 95% CI, 1.36 to 7.44; P = .01) and those referred from oncology clinics and community oncology resources (OR = 2.97; 95% CI, 1.34 to 6.58; P = .01) were most likely to enroll onto the study. Referral from oncology clinics was associated significantly with participation in genetic counseling (OR = 5.46; 95% CI, 1.44 to 20.60; P = .01).

Conclusion
Despite receiving a large number of referrals, only a small subset of women were eligible for enrollment. Oncology settings were the most effective at identifying eligible African American women and general medical practices were the least effective. Factors associated with enrollment included having a stronger family history of cancer and being referred from oncology clinics and community oncology resources. Referral from oncology clinics was the only factor associated significantly with participation in genetic counseling. Education about hereditary breast cancer may be needed among primary care providers to enhance appropriate referral of African American women to genetic counseling for *BRCA1/2* mutations.

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INTRODUCTION

Despite intensive efforts, African American participation in cancer research remains limited.[1-4] In addition, African American enrollment in research on *BRCA1* and *BRCA2* (*BRCA1/2*) mutations is low.[5,6] Recruitment for these studies is a complex process that begins with identifying potentially eligible participants from referral sites, inviting eligible individuals to enroll onto the study, and completing enrollment and study procedures.[7,8] Little is known about the process of recruiting African Americans to participate in clinical research for *BRCA1/2* mutations or factors that influence outcomes at each stage of the process. The goals of this study were to determine the proportion of women who are referred to a *BRCA1/2* genetic counseling research program who were

eligible for participation; determine the proportion of eligible women who enroll onto the study; determine the proportion of women who participate in genetic counseling; and evaluate the role of referral site and participant characteristics on each phase of the recruitment process.

PATIENTS AND METHODS

Study Population

This study was approved by the Institutional Review Board at the University of Pennsylvania. To be eligible for participation, women had to self-identify as being African American or black, be at least 18 years of age, and have a minimum 5% to 10% prior probability of having a *BRCA1/2* mutation. Participant recruitment was initiated in February 2003. To be included in the analysis of study enrollment, potential participants had to have a defined eligibility status, and if eligible, had to have been contacted about enrollment.

Procedures

Potential participants were identified through a referral network that included seven clinical institutions and community oncology resources (eg, breast cancer support groups, health fairs) located in Philadelphia, PA. At all clinical referral sites, the following information was provided in brochures and flyers given to all African American women by physicians and clinic staff: a new research program specifically for African American women was available, and eligible women would receive counseling and education about hereditary cancer. At community oncology resources, study brochures and flyers were distributed by research staff. It is important to note that some women (n = 19) were referred to the study while participating in an epidemiologic protocol designed to identify genetic risk factors for breast cancer or learned about the study through another breast cancer risk counseling program at the University of Pennsylvania (n = 14). However, these women did not receive genetic counseling or clinical genetic testing for *BRCA1/2* mutations before being referred; thus, there was no overlap with the genetic counseling research program. Furthermore, enrollment was not significantly different among women referred from the epidemiologic study and counseling program ($\chi^2 = 1.20$; $P = .27$). Referral forms were completed by women interested in learning more about genetic counseling and included the following information: racial background, address, birth date, and personal and family history of cancer.

After referral, eligibility was determined by the study genetic counselor (L.K.) and enrollment was initiated by mailed invitation. Specifically, eligible women were mailed an invitation letter that described the study purpose and procedures. Women who did not opt out of enrollment by returning a reply card were contacted by telephone to complete the baseline interview. Before completing the baseline interview, verbal consent for study enrollment was obtained by a trained research assistant using a standardized consent script that described the study purpose and procedures, and possible risks and benefits. After women gave consent and enrolled onto the study, the baseline interview was completed. At the end of the baseline interview, women were invited to participate in pretest genetic counseling. For women who accepted the invitation, a genetic counseling appointment was scheduled for a convenient time, including evenings and weekends. Women were not offered a financial incentive for study enrollment and costs for transportation expenses were paid by grant funds. Genetic testing expenses were paid by participant's insurance company or by institutional funds at the Abramson Cancer Center (Philadelphia, PA).

Outcomes

Eligibility. Women who had a 5% to 10% prior probability of having a *BRCA1/2* mutation were eligible for study enrollment. Women who did not have a 5% to 10% prior probability were ineligible.

Study enrollment. Women who consented for study enrollment, completed the baseline interview, and accepted the invitation for pretest genetic counseling were categorized as study enrollees. Women who consented for study enrollment, completed the baseline interview, and declined genetic counseling were also categorized as study enrollees if they agreed to participate in follow-up telephone interviews. Women who actively declined study enrollment and those who passively declined enrollment by not responding to multiple attempts to complete the baseline interview were categorized as nonenrollees.

Participation in genetic counseling. Women who completed pretest genetic counseling were categorized as counseling participants. Women who enrolled in the study but declined genetic counseling and those who did not complete counseling after accepting the invitation were categorized as counseling nonparticipants.

Recruitment Variables

Referral site. Women were categorized as being referred from oncology resources (eg, oncology clinics [ONCs], mammography facilities), general medical resources (eg, internal medicine, obstetric/gynecology practices), or community oncology resources based on the setting from which they were referred.

Referral personnel. Women were categorized as having been referred to the study by physicians or clinic/research staff.

Eligibility Variables

Clinical factors. Age, personal history of breast and/or ovarian cancer, and family history of cancer were obtained by self-report at referral. Because it is standard practice in genetic counseling to construct a three-generation pedigree,[9,10] we calculated the total number of first-, second-, and third-degree relatives affected with breast and/or ovarian cancer. Women were categorized as having two or more, or less than two affected relatives.

BRCA1/2 prior probability. Probability of having a *BRCA1/2* mutation was estimated based on the individual's personal and family history of breast and/or ovarian cancer using prior probability models and mutation prevalence tables.[11-14] Women were categorized as being at moderate (5%) or high (10% or higher) risk of having a *BRCA1/2* mutation.

Participant Characteristics

Sociodemographics. Marital status, education level, employment status, and income were obtained by self-report at the baseline interview.

Risk perception. Perceived risk of having a *BRCA1/2* mutation was evaluated at baseline using one previously validated Likert-style item[3,15,16] that asked women to indicate how likely it was that they had a *BRCA1/2* mutation (1 = not at all likely to 4 = definitely). We recoded this item into a dichotomous variable (likely *v* not likely) based on the distribution of responses.

RESULTS

Eligibility for Study Participation

As shown in Figure 1, since initiating recruitment in February 2003 to August 2004, 783 African American women were referred to the study. Most women 492 (63%) were referred from general medical practices (GMPs), 200 (25%) were referred from oncology clinics (ONCs), and 91 (12%) were referred from community oncology resources (COMs). All women referred to the study self-identified as being African American or black.

The referral rate equaled the number of eligible women divided by the total number of women referred to the study. Of the 783 women referred, 164 (21%) were eligible for participation and 619 (79%) were ineligible because their personal or family history of cancer was not suggestive of hereditary disease. Eligible women were most likely to be referred from ONCs (44%) compared with COMs (23%) and GMPs (11%; $\chi^2 = 96.80$; $P = .0001$). Ineligible women and those who were eligible for participation but pending contact for enrollment were excluded from subsequent analyses; thus, the data presented below evaluate study enrollment among 157 eligible women (95% of the 164 eligible women).

Predictors of Study Enrollment

The enrollment rate equaled the number of women who enrolled onto the study divided by the total number of eligible women. Of 157 eligible women, 98 (62%) enrolled onto the study. As listed in Table 1, family history was associated significantly with enrollment. Women who had two or more affected relatives were most likely to enroll. Study enrollment was also significantly greater among women referred from ONCs and COMs compared with GMPs. There was also a trend for affected women to be more likely to enroll onto the study compared with unaffected women. No other factors were associated significantly with study enrollment.

We used logistic regression analysis to identify factors having independent associations with study enrollment. Because study enrollment was not significantly different among women referred from ONCs and COMs, we combined these groups into one category and evaluated referral site as a two-level variable (ONC/COM *v* GMP) in the regression model. Referral site was not associated significantly with family history of cancer ($\chi^2 = 0.74$; $P = .69$) but was related to personal history of disease ($\chi^2 = 29.83$; $P = .001$); however, this association did not result in multicollinearity (r for the coefficients $= -0.41$). Therefore, variables that had a bivariate association of $P < .20$ with enrollment (referral site, cancer history, and family history) were included in the regression model.

Only referral site and family history had significant independent associations with study enrollment. Women who had two or more affected relatives were three times more likely to enroll onto the study compared with those who had fewer affected relatives (odds ratio [OR] = 3.18; 95% CI, 1.36 to 7.44; $P = .01$). Compared with women referred from GMPs, those referred from ONCs and COMs were about three times more likely to enroll (OR = 2.97; 95% CI, 1.34 to 6.58; $P = .01$). The effect for cancer history was not significant (OR = 2.00; 95% CI, 0.78 to 5.14; $P = .15$). We reran the logistic regression model excluding women referred from the epidemiologic protocol and the other risk counseling program; the results were unchanged (family history: OR = 3.34, 95% CI, 1.23 to 9.11, $P = .02$; referral site: OR = 2.93, 95% CI, 1.24 to 6.90, $P = .01$).

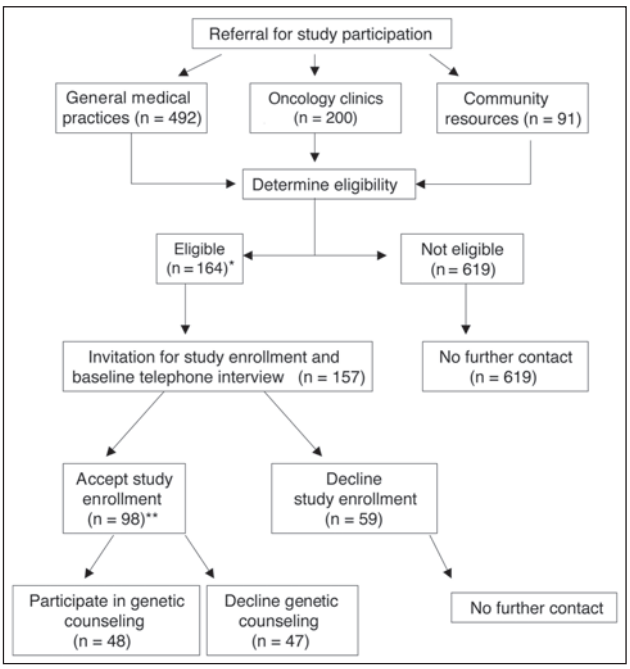

Fig 1. Overview of study procedures. *Women pending contact for study enrollment (n = 7) were excluded from the analysis of study enrollment. **Women undecided about genetic counseling (n = 3) were excluded from the analysis of participation in genetic counseling.

Predictors of Participation in Genetic Counseling

The rate for participation in genetic counseling equaled the number of women who participated in genetic counseling divided by the number of eligible study enrollees. Overall, 48 (50%) of eligible study enrollees (n = 95) participated in genetic counseling (30% of all eligible women [n = 157] contacted for study enrollment). (Three women who enrolled onto the study were undecided about participation in genetic counseling and were excluded from the analysis of genetic counseling participation; therefore, the denominator for this analysis is 95 women.) As listed in Table 2, women with greater education and those at high risk for having a *BRCA1/2* mutation were most likely to participate in genetic counseling. Women referred from ONCs were

Table 1. Factors Associated With Study Enrollment (n = 157)

Variable	Level	Total		Enrollment Status					
				Enrollees		Nonenrollees			
		No.	%	No.	%	No.	%	χ^2	*P*
Age, years*	≤ 50	87	57	58	67	29	33	0.43	.51
	> 50	65	43	40	62	25	38		
Cancer history	Affected	98	62	66	67	32	33	2.70	.10
	Unaffected	59	38	32	54	27	46		
Family history	Two or more	84	54	59	70	25	30	4.71	.03
	Fewer than two	73	46	39	53	34	46		
BRCA1/2 prior probability	High	78	50	52	67	26	33	1.19	.28
	Moderate	79	50	46	58	33	42		
Referral site	Oncology	85	54	62	73	23	27	13.47	.001
	Community	20	13	14	70	6	30		
	General	52	33	22	42	30	58		
Referral source	Clinic/research staff	148	94	91	61	57	38	0.96	.33
	Physician	9	6	7	78	2	22		

*Data for age were missing for five participants.

also most likely to participate in genetic counseling. Affected women were also more likely to participate in genetic counseling compared with unaffected women; however, this effect was not statistically significant ($P = .07$). No other factors were associated significantly with participation in genetic counseling.

To identify factors having independent association with participation in genetic counseling, we used logistic

Table 2. Factors Associated With Participation in Genetic Counseling (n = 95)

Variable	Level	Total		Participation Status				
				Counseling Participants		Counseling Nonparticipants		
		No.	%	No.	%	No.	%	χ^2
Age, years	≤ 50	56	59	29	52	27	48	0.09
	> 50	39	41	19	49	20	51	
Marital status	Married	33	35	20	61	13	39	2.06*
	Not married	62	65	28	45	34	55	
Education level	≥ Some college	67	71	39	58	28	42	5.37†
	≤ High school	28	29	9	32	19	68	
Employment status	Employed	65	68	34	52	31	48	0.26
	Not employed	30	32	14	47	16	53	
Income level	> $35,000	49	52	26	53	23	47	0.26
	≤ $35,000	46	48	22	48	24	52	
Cancer history	Affected	65	68	37	57	28	43	3.37*
	Unaffected	30	32	11	37	19	63	
Family history	Two or more	56	59	30	54	26	46	0.51
	Fewer than two	39	41	18	46	21	54	
BRCA1/2 prior probability	High	51	54	31	61	20	39	4.64†
	Moderate	44	46	17	39	27	61	
Referral site	Oncology	60	63	38	63	22	37	12.59‡
	Community	14	15	6	43	8	57	
	General	21	22	4	19	17	81	
Referral source	Clinic/research staff	88	93	45	51	43	49	0.18
	Physician	7	7	3	43	4	57	
BRCA1/2 perceived risk	Likely	65	69	36	55	29	45	2.44*
	Not likely	29	31	11	38	18	62	

*$P < .20$.
‡$P < .01$.
†$P < .05$.

regression analysis. Because participation in genetic counseling differed among women referred from ONCs, COMs, and GMPs, we used dummy variables to evaluate the effect of referral site; women referred from GMPs were used as the reference group. As listed in Table 3, clinical factors and sociodemographics were not associated significantly with participation in genetic counseling. The addition of referral site improved the overall fit of the model (likelihood ratio test = 14.23; $P = .001$); however, only the effect for the comparison of the ONCs to GMPs was significant. We reran the logistic regression model excluding women referred from the epidemiologic study and the other risk counseling program, and the results were unchanged (OR = 5.09, 95% CI, 1.27 to 20.45, $P = .02$ for the comparison of ONCs to GMPs and OR = 2.54, 95% CI, 0.47 to 13.83, $P = .28$ for the comparison of COMs to GMPs).

DISCUSSION

To our knowledge, this is the first empirical study to evaluate the process of recruiting (eg, determination of the proportion of eligible women referred to the study and rates of study enrollment and participation in genetic counseling) African American women to genetic counseling research for *BRCA1/2* mutations. Despite receiving a large number of referrals, only 21% of women referred to the study were eligible for enrollment; eligible women were most likely to be identified from oncology resources. This finding is not surprising given the fact that hereditary breast cancer is rare and *BRCA1/2* mutations account for only approximately 5% to 10% of all breast cancer occurrences.[17-19] Thus, most women in the general population, including those receiving care in oncology settings, are not likely to have a personal and family history cancer that is suggestive of hereditary disease and be eligible for enrollment onto genetic counseling research.

Overall, 62% of eligible women enrolled onto the study and of the eligible enrollees, 50% participated in genetic counseling. Although prior studies have shown that African Americans report concerns about genetics research[20,21] and may not participate in genetic registries,[4] our enrollment and participation rates are similar to those reported for hereditary breast cancer studies conducted with predominantly white populations.[22,23] It is important to note that only half of eligible women participated in genetic counseling. This may indicate that acceptance of genetic testing may be even lower among African American women than previously reported[6,24]; however, participation in genetic counseling and testing may be greater among women who are specifically seeking these services. Future studies should evaluate reasons for participating and not participating in genetic counseling among African American women.

We found that women who had a stronger family history of cancer were most likely to enroll onto the study. However, family history was not associated with participation in genetic counseling. This suggests that family history may motivate participation in the initial aspects of hereditary breast cancer research, but may not translate into completion of study procedures. Despite this, collecting information on family history from African American women in clinical settings is important to ensure that women with an increased risk for *BRCA1/2* mutations are informed about the availability of programs designed to provide education and counseling, and are referred for participation. Participation in genetic counseling may be beneficial to African American women to increase knowledge

Table 3. Logistic Regression Analysis of Participation in Genetic Counseling

Variable	Levels	OR	95% CI	*P*
Cancer history	Affected	1.69	0.59 to 4.82	.33
	Unaffected (referent)	1.00		
BRCA1/2 prior probability	High	1.74	0.69 to 4.38	.24
	Moderate (referent)	1.00		
Education level	> Some college	2.54	0.89 to 7.28	.08
	≤ High school (referent)	1.00		
Marital status	Married	1.11	0.41 to 2.97	.84
	Not married (referent)	1.00		
BRCA1/2 perceived risk	Likely	1.97	0.71 to 5.49	.19
	Not likely (referent)	1.00		
Referral site	ONC	5.46	1.44 to 20.60	.01
	GMP (referent)	1.00		
	COM	3.24	0.61 to 17.31	.17
	GMP (referent)	1.00		

NOTE. Variables that had a bivariate association of $P < .20$ with participation in genetic counseling were included in the logistic regression model. Inclusion of personal history of cancer and referral site did not result in multicollinearity (r for the coefficients < 0.20).
Abbreviations: OR, odds ratio; ONC, oncology clinic; GMP, general medical practice; COM, community oncology resource.

about breast cancer risk factors and to provide information about options for cancer prevention and control.

We also found that referral site was associated significantly with study enrollment and participation in genetic counseling. An important consideration, however, is that eligible women were most likely to be identified from ONCs. However, previous studies have shown that African American participation in cancer prevention and control research and treatment trials is limited, even though participants are identified from oncology settings and may have a vested interest in study enrollment to obtain cancer treatment or support services.[1,2,15,25] Our findings suggest that even though recruitment from oncology settings has not translated into high rates of African American participation in most types of cancer research, African American women who are referred from oncology settings may be willing to enroll onto hereditary breast cancer research studies and participate in genetic counseling. It is possible that women referred from oncology settings were most likely to participate in genetic counseling because of increased knowledge about hereditary breast cancer or greater perceived value of genetic risk information.[6] Thus, oncology settings can be an effective resource for identifying African American women who are eligible to participate in hereditary breast cancer research, and referral from these settings may translate into completion of study procedures. Future studies are needed to identify motivations for participating in genetic counseling among women referred from different settings.

In considering the results of this study, some limitations should be noted. First, we were not able to evaluate the effects of sociodemographics on study enrollment. This information was collected after enrollment; however, we did compare participants and nonparticipants in genetic counseling in terms of sociodemographics, and we also compared study enrollees and nonresponders in terms of some baseline variables. An additional limitation is that more than one type of referral personnel was used. Thus, it is possible that women heard about the study through multiple sources or received more detailed information about the study from clinic staff or physicians. However, referral source was not associated significantly with study enrollment; therefore, it is not likely that any potential variation in information received about the study influenced enrollment decisions. However, our study was not powered to detect differences in study enrollment or participation in genetic counseling based on referral from different types of personnel. Thus, experimental studies are needed to compare the effects of different referral sites and sources on African American enrollment in hereditary breast cancer research. Within these designs it will be especially important to evaluate the impact of race of the individual making the referral and completing enrollment procedures on participation decisions.

Despite these limitations, this study highlights the importance of using multiple referral sites to identify African American women at increased risk for hereditary breast cancer. Our findings suggest that African American women at increased risk for having a *BRCA1/2* mutation are receptive to enrolling onto genetic counseling research; however, one's family history of cancer and the referral site may influence decisions about study enrollment and participation in genetic counseling. Increasing awareness about the availability of hereditary breast cancer research among African American women in oncology settings and developing strategies to identify women at increased risk for hereditary disease may enhance African American participation in genetic counseling research. It may also be important to enhance knowledge about hereditary breast cancer and genetic counseling among physicians and clinic staff in GMPs. Although most African American women were referred from general medical practices, fewer eligible women were referred from these sites. Recent studies have shown knowledge about hereditary cancer is limited among primary care providers and most primary care providers believe that they are not qualified to provide genetic services.[26,27] Educational efforts about hereditary cancer may enhance recognition of women at increased risk for *BRCA1/2* mutations in settings where a greater number of African American women may be receiving health care.

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Authors' Disclosures of Potential Conflicts of Interest

The authors indicated no potential conflicts of interest.

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Short Report

Psychological functioning in African American women at an increased risk of hereditary breast and ovarian cancer

Halbert CH, Kessler L, Collier A, Paul Wileyto E, Brewster K, Weathers B. Psychological functioning in African American women at an increased risk of hereditary breast and ovarian cancer. Clin Genet 2005: 68: 222–227. © Blackwell Munksgaard, 2005

Despite attention to psychological issues during genetic counselling and testing for hereditary breast and ovarian cancer risk, limited information is available on cancer-specific distress among African American women being targeted for participation in counselling and testing. Therefore, the purpose of this study is to examine cancer-specific distress in African American women at an increased risk of hereditary breast and ovarian cancer and to identify factors having significant associations with distress in this population. Respondents were 141 African American women identified for participation in genetic counselling and testing for BRCA1/2 mutations. Overall, respondents reported moderate levels of cancer-specific distress. Younger age (coefficient = 6.0, p = 0.001), being unemployed (coefficient = −5.0, p = 0.01), and having a personal history of cancer (coefficient = 5.0, p = 0.02) had significant associations with intrusion. Younger age was also associated significantly with greater avoidance (r = 6.0, p = 0.02). These results suggest that African American women aged 50 and younger, those who are unemployed and women with a personal history of breast or ovarian cancer may be the most vulnerable to experiencing elevated levels of distress during genetic counselling and testing. Greater attention to psychological issues, including concerns about cancer and cancer risks, may be needed during genetic counselling and testing for BRCA1/2 mutations with these women.

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Key words: African American – BRCA1 and BRCA2 mutations – psychological functioning

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Based on studies, showing that the prevalence of risk-conferring BRCA1 and BRCA2 (BRCA1/2) mutations ranges between 16 and 21% in African Americans (1, 2), African American women are being targeted for participation in genetic counselling and testing. Attention to psychological issues is an important aspect of genetic counselling and testing (3); it is recommended that psychological support be provided to individuals considering testing and those receiving results (4, 5). Previous research has showed that African American women are vulnerable to experiencing cancer-specific distress (6, 7); however, few studies have identified factors that contribute to this vulnerability. One study found that sociodemographics were most important to psychological functioning in African American and Caucasian women (8). However, for a number of historical and social reasons, African Americans and Caucasians differ on sociodemographics (8, 9). Thus, confounding with ethnicity makes it difficult to understand the effects of sociodemographics on psychological functioning in studies that compare African American and Caucasian women. Within-group comparisons are needed to identify factors that are associated with psychological functioning in African American women being targeted for participation in genetic counselling and testing for BRCA1/2 mutations.

This study evaluates cancer-specific distress in African American women at an increased risk of hereditary cancer and identifies factors

associated significantly with distress. Based on prior research showing that sociodemographics influence psychological functioning (8), we hypothesized that having fewer socioeconomic resources would be associated with greater distress. We also predicted that distress would be greater among women affected with cancer because of more direct experiences with the disease. We also hypothesized that BRCA1/2 risk perception would contribute to distress. A substantial amount of complex information needs to be covered during pretest education and test result disclosure (10); identifying African American women in greatest need for psychological support may facilitate the process of providing genetic counselling.

Materials and methods

Participants

Respondents were 141 African American women at an increased risk of having a BRCA1/2 mutation who were recruited from the University of Pennsylvania (Penn) and the Georgetown University Medical Center (GUMC). Women had to self-identify as being Black or African American and have a 5–10% prior probability of having a BRCA1/2 mutation to be eligible for participation (11, 12). The IRB at both centres approved the research. It should be noted that some women at Penn ($n = 22$) provided a blood sample as part of a separate study to understand genetic risk factors for breast cancer before being contacted for the present study. However, clinical genetic testing for BRCA1/2 mutations was not performed and none of these women received genetic counselling. Study site was controlled for in the statistical analysis.

Procedures

Respondents were recruited into the study using similar procedures at both centres. Specifically, women were given written information about the study by a physician or clinic staff during an office visit or community event. Women who were interested in learning more about the study were asked to complete a referral form that included their racial background, contact information, date of birth and personal and family history of breast and/or ovarian cancer. At GUMC, women were identified from mammography and oncology clinics; at Penn, women were identified from the University of Pennsylvania Health System (UPHS), other health care facilities and community resources. Genetic counsellors at both sites reviewed referral forms to determine eligibility.

Following referral, eligible women were contacted to complete a baseline telephone interview. The response rate to the baseline was 62% at GUMC and 65% at Penn. As the majority of women were recruited at Penn, we compared these women who completed the baseline to decliners in terms of clinical factors. Women at moderate risk ($\chi^2 = 4.04$, $p = 0.04$) and those with fewer relatives affected with cancer ($\chi^2 = 8.33$, $p = 0.004$) were significantly the most likely to decline the baseline. Cancer history and age were not associated significantly with declining the baseline. The baseline was a structured 40-min interview that measured sociodemographics, BRCA1/2 risk perception and cancer-specific distress. Identical questions were used to evaluate these variables in the surveys completed at Penn and GUMC. At the end of the survey, women were invited to participate in genetic counselling. This report focuses on data collected during the baseline before genetic counselling.

Measures

Predictor variables

Study site. The site from which women were recruited was obtained from research records.

Sociodemographics. Likert-style items were used to obtain marital status, income, education and employment status. We re-coded these items into dichotomous variables based on the distribution of responses. Respondents were categorized as being ≤ 50 or >50, because this was the criteria used for determining whether one's family history of cancer was suggestive of hereditary disease.

Clinical factors. Personal history of breast and/or ovarian cancer and the number of relatives affected with these diseases were obtained. Because the total number of affected relatives is used to determine whether someone's family history is suggestive of hereditary cancer (12), family history was calculated as the total number of affected relatives. Family history was re-coded into a dichotomous variable (≥ 2 vs <2 relatives) based on the frequency of responses. Probability of having a BRCA1/2 mutation was estimated based on the respondent's personal and family history of cancer using prior probability models and mutation prevalence tables (12–14). Respondents

were categorized as being at moderate (5%) or high (>10%) risk of having a BRCA1/2 mutation.

Perceived risk. Perceived risk was evaluated using a Likert-style item that asked respondents how likely it was that they had a BRCA1/2 mutation. This item has been used in previous research on psychological functioning in African American and Caucasian women seeking education and counselling about hereditary breast and ovarian cancer (5).

Outcome variable

Cancer-specific distress. We used the Impact of Event Scale (IES) (15) to evaluate cancer-specific distress. The IES is a 15-item Likert-style instrument that measures the frequency of intrusive thoughts about cancer and attempts to avoid cancer-related thoughts and feelings. The IES has been used in previous studies on psychological functioning in African American women (6, 9, 16). The avoidance and intrusion scales had excellent internal consistency (Cronbach's alpha = 0.85 and 0.86, respectively).

Data analysis

We first generated descriptive statistics to characterize respondents in terms of sociodemographics, clinical variables and cancer-specific distress. Then, we performed bivariate analyses to evaluate differences in predictor variables and distress between women recruited at Penn and GUMC. Because distress scores were not normally distributed, we used non-parametric analysis of variance, using the Kruskal–Wallis test, to evaluate the association between distress and predictor variables. We used multivariate median regression analysis (17) to identify predictors of cancer-specific distress while controlling for study site and variables associated significantly with completing the baseline. Predictor variables that had a significant association of $p < 0.10$ with distress were included in the regression models.

Results

Sample characteristics

Table 1 shows the characteristics of respondents. All women referred to the study self-identified as being African American or Black. There were no differences in sociodemographics, perceived risk or distress between respondents recruited at Penn and GUMC; however, a greater number of women at a high risk of having a BRCA1/2 mutation ($\chi^2 = 5.65$, $p = 0.02$) and women with a personal history of cancer ($\chi^2 = 6.06$, $p = 0.01$) were recruited at GUMC. There were no differences in family history between respondents recruited at Penn and GUMC ($\chi^2 = 0.26$, $p = 0.61$).

Descriptive information on cancer distress

According to clinical criteria for cancer-specific distress (18, 19), respondents reported moderate levels of distress. The mean (SD) score for the total IES was 17.56 (16.75). The mean (SD)

Table 1. Sample characteristics (n = 141)

Variable	Level	n (%)
Study site	Penn	121 (87)
	GUMC	18 (13)
Marital status	Married	50 (35)
	Not married	91 (65)
Education level	Some college or college graduate	101 (72)
	High school graduate or less	40 (28)
Employment status	Employed	99 (70)
	Not employed	42 (30)
Income level	Greater than $35,000	75 (53)
	Less than or equal to $35,000	66 (47)
Cancer history[a]	Affected	98 (70)
	Unaffected	43 (30)
Family history of cancer	≥2 relatives	86 (61)
	<2 relatives	55 (39)
BRCA1/2 Prior probability	High	81 (57)
	Moderate	60 (43)

Cancer history: Affected = has a personal history of breast and/or ovarian cancer; unaffected = does not have a personal history of breast and/or ovarian cancer.

scores for intrusion and avoidance were 8.28 (8.30) and 9.29 (9.38), respectively. The median score for both intrusion and avoidance was 6.0.

Association between cancer distress and sociodemographics, clinical factors and perceived risk

As showed in Table 2, younger age was associated significantly with greater avoidance and intrusion. However, being unemployed was only associated significantly with greater intrusion. Of the clinical factors, cancer history was associated significantly with intrusion and was marginally associated with avoidance. Higher probability of having a BRCA1/2 mutation was associated significantly with greater avoidance, whereas BRCA1/2 risk perception was associated significantly with intrusion. Income, marital status, education and family history were not associated significantly with avoidance or intrusion.

Multivariate regression model of cancer distress

As showed in Table 3, only age had a significant effect on avoidance; avoidance was greatest among women $\leq$50. Cancer history, employment status and BRCA1/2-perceived risk had significant effects on intrusion. Women affected with cancer, those who were not employed and women who believed that they were at the risk of having a BRCA1/2 mutation reported greater intrusion, compared to unaffected women, those who were employed and women who did not believe that they were at the risk of having a BRCA1/2 mutation.

Discussion

To our knowledge, this is the first empiric study to evaluate cancer-specific distress in African American women at an increased risk through having a BRCA1/2 mutation. Similar to Caucasian women undergoing genetic counselling (20), African American women reported moderate levels of distress. Although previous research has shown that income, marital status and education contribute to psychological functioning in African American women (8), these factors were not associated with distress in the present study. However, women $\leq$50 were significantly most likely to report greater avoidance and intrusion. Younger age has been associated with cancer-specific distress in African American women in other studies (16, 21). In families at the risk of hereditary breast–ovarian cancer, these diseases occur with an early age of onset and BRCA1/2 mutation carriers have an increased risk of developing breast and ovarian cancer (22–25). It is possible that distress was greater in younger women because of more frequent thoughts about their cancer risk and greater attempts to avoid thinking about their risk of disease.

Table 2. Bivariate association between cancer-specific distress and sociodemographic and clinical factors

Variable	Level	Avoidance median	Non-parametric comparison	Intrusion median	Non-parametric comparison
Age	$\leq$50	10.0	5.89[a]	9.0	10.56[a]
	>50	4.0		3.0	
Marital status	Married	7.0	0.006	9.0	0.38
	Not married	6.0		6.0	
Education level	$\geq$Some college	6.0	0.0001	6.0	0.01
	$\leq$High school	6.0		6.0	
Employment status	Employed	6.0	2.31	4.0	4.70[b]
	Not employed	9.5		10.0	
Income level	>$35,000	6.0	2.07	5.0	0.73
	<$35,000	8.0		6.5	
Cancer history	Affected	7.0	2.63[c]	6.5	4.69[b]
	Unaffected	4.0		3.0	
Family history of cancer	$\geq$2 relatives	6.0	0.02	6.0	0.67
	<2 relatives	6.0		6.0	
BRCA1/2 Prior probability	High	7.0	3.33[c]	8.0	2.37
	Moderate	4.0		4.0	
BRCA1/2 Perceived risk	Likely	6.0	0.86	8.0	8.43[b]
	Not likely	4.0		1.5	

[a]$P < 0.01$, [b]$P < 0.05$, [c]$P < 0.10$.

Table 3. Multivariate regression model of distress

Distress variable	Predictor variable	Coefficient	p-value
Avoidance	Study site[a]	−2.0	0.65
	Family history[b]	0.0	1.00
	BRCA1/2 prior probability[c]	−3.0	0.24
	Age[d]	6.0	0.02
	Cancer history[e]	3.0	0.32
Intrusion	Study site[a]	−1.0	0.71
	Family history[b]	0.0	1.00
	BRCA1/2 prior probability[c]	0.0	1.00
	Age[d]	6.0	0.001
	Cancer history[e]	5.0	0.02
	Employment status[f]	−5.0	0.01
	BRCA1/2 perceived risk[g]	5.0	0.002

[a]Study site: Penn *vs* GUMC.
[b]Family history: $\geq$2 relatives *vs* <2 relatives.
[c]BRCA1/2 prior probability: high *vs* moderate risk.
[d]Age: $\leq$50 *vs* >50.
[e]Cancer history: affected *vs* unaffected.
[f]Employment status: employed *vs* not employed.
[g]BRCA1/2 perceived risk: likely *vs* not likely.

Consistent with other reports (21, 26), BRCA1/2 risk perception was associated significantly with distress. However, risk perception only had a significant effect on intrusion. Similarly, cancer status was only associated significantly with intrusion. Women with a personal history of cancer and who have a BRCA1/2 mutation have an increased risk of developing contralateral disease (24, 27–29). It is possible that intrusion was higher among affected women because of more frequent thoughts about the possibility of cancer recurrence. We also found that unemployed women reported greater intrusion than employed women. It is possible that unemployed women were more distressed because of worry about the ability to pay for cancer screening tests needed to manage their cancer risk. However, studies are needed to evaluate perceived risk of developing cancer again and the impact of diagnosis and treatment on intrusion in African American breast cancer survivors at an increased risk of hereditary disease. Studies are also needed to identify factors that are associated with risk management behaviours in African American women at an increased risk of hereditary cancer. It will be especially important to identify barriers to cancer screening in this population.

In considering the results of the present study, some limitations should be noted. First, approximately 60% of women completed the baseline telephone interview. However, our participation rates are similar to those reported in other cancer research with African American women (8, 30). Our results may have limited generalizability, because women at moderate risk and those with fewer affected relatives were most likely to decline completing the baseline. The cross-sectional nature of the data is another limitation; longitudinal studies are needed in order to evaluate changes in cancer-specific distress in African American women.

Despite these potential limitations, the results of this study have important implications for genetic counselling targeted to African American women. Prior studies have showed that psychological functioning may influence the comprehension of genetic risk information (31) and testing decisions (9, 32). Our results shed light on African American women who might have the greatest need for psychological support during counselling. More extensive discussion of reactions to different testing scenarios and concerns about the familial impact of genetic testing as well as identification of culturally sensitive coping strategies and sources for emotional support (e.g. religion and spirituality) may increase the cultural sensitivity of genetic counselling for African American women. Exploration of past experiences with cancer, including the experiences of other family members, may be another strategy for providing culturally tailored genetic counselling to these women (33). As African American women are targeted for participation in genetic counselling and testing, it will be important to design protocols that are sensitive to their psychological needs.

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Breast cancer screening behaviors among African American women with a strong family history of breast cancer

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Abstract

Background. Despite the importance of breast cancer screening to reduce morbidity and mortality, limited information is available on screening practices among African American women with a family history that is suggestive of hereditary breast cancer.

Objectives. To describe adherence to breast cancer screening recommendations among African American women with a family history that is suggestive of hereditary disease.

Methods. Participants were unaffected African American women ($n=65$) who had a family history of cancer that was suggestive of hereditary breast cancer. Breast cancer screening practices were evaluated by self-report. The study was conducted at the University of Pennsylvania in Philadelphia, PA. Women were recruited to participate in the study from February 2003–December 2005.

Results. Most women were adherent to recommendations for mammography (75%) and CBE (93%). A sizeable minority of women (41%) also performed excessive BSE. Being older than age 50 was associated significantly with mammography adherence (FET <0.05). Employment had a significant independent association with BSE; unemployed women were most likely to perform excessive BSE (OR $=3.28$, 95% CI: 1.05, 10.21, $p<0.05$).

Conclusions. The results of this study suggest a complex pattern of breast cancer screening practices among African American women at increased risk for hereditary breast cancer.

Keywords: African American; Hereditary breast cancer; Screening practices

Introduction

Breast cancer screening plays an important role in reducing morbidity and mortality among African American women. Breast cancer screening recommendations include annual mammography and CBE and monthly BSE (American Cancer Society, 2006). However, women at increased risk for disease may be advised to consider starting screening earlier or having more frequent tests (American Cancer Society, 2006). Previous research has shown that most Caucasian women at increased risk for hereditary disease are adherent to mammography guidelines whereas Kinney and colleagues found that only about 30% of African American women at increased risk for hereditary disease were adherent to recommendations (Isaacs et al., 2002; Kinney et al., 2002). These results have limited generalizability because participants were from a single family identified from a hereditary breast cancer registry or included a small number of African American women. Empirical data on breast cancer screening before genetic counseling are needed among more generalizable samples of African American women at risk for hereditary breast cancer. Therefore, we evaluated these practices among women who had a family history of breast cancer that was suggestive of hereditary disease and identified factors having independent associations with screening. Based on previous research showing a positive

Abbreviations: CBE, Clinical Breast Exam; BSE, Breast Self-Examination; FET, Fisher's Exact Test.

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association between cancer-related worry and screening (Brain et al., 1999), we also evaluated the relationship between screening and cancer-specific distress.

Methods

Participants were unaffected African American women ($n=65$) who had a minimum 5% to ≥10% prior probability of having a BRCA1/2 mutation. The study recruitment and enrollment procedures have been described in detail elsewhere (Halbert et al., 2005a) and are summarized here. Women were identified from clinical and community settings located in Philadelphia, PA from February 2003 through December 2005. Women completed a referral form that obtained race, contact information, and personal and family history of breast and ovarian cancer. Referral forms were reviewed by the study genetic counselor (LK) and family history information was entered into risk estimation models (Domchek et al., 2003) to determine prior probability of having a BRCA1 or BRCA2 (BRCA1/2) mutation. Women who had a 5% to ≥10% prior probability of having a mutation based on their family history of cancer were contacted to complete enrollment and the baseline telephone interview. Verbal consent for enrollment was obtained using a standardized script. After women provided consent and enrolled in the study, the baseline was completed. The study enrollment rate was 62% (Halbert et al., 2005a). At the end of the baseline, women were invited to participate in genetic counseling. The present paper focuses on cancer screening behaviors reported at baseline.

All data were collected by self-report during the baseline. Variables from theoretical models of health behavior (Janz et al., 2002) and previous research on breast cancer screening practices among African American women were evaluated as possible predictors of screening behaviors (Phillips and Wilbur, 1995; Rosenberg et al., 2005). These variables included *sociodemographics* such as household income. Clinical factors included BRCA1/2 prior probability (≥10% or 5%) according to risk estimation models and family history of breast and/or ovarian cancer (≥2 or <2 relatives). *Psychological variables* included perceived risk of developing cancer and cancer-specific distress. Perceived risk was measured using a Likert-style item that asked women to rate their chances of getting breast cancer compared to other women their age (Hughes et al., 1996) and cancer-specific distress was measured using the Impact of Events Scale. *Breast cancer screening practices* were evaluated using items from previous research (Lerman et al., 2000; Hughes et al., 1996). BSE was evaluated by one item that asked women how many times they had examined their breasts during the past three months. Adherence to BSE recommendations was determined based on ACS guidelines. To evaluate mammography and CBE utilization, women were asked if they had ever had these screening tests (yes or no). Mammography adherence was determined based on the last screening date using methods from prior research (Lerman et al., 2000). This same approach was used to determine CBE adherence. Since prior studies have shown that African American women with a family history of breast cancer may have a tendency to over utilize BSE (Hughes et al., 1996; Kinney et al., 2002), we focused on BSE over-adherence in this report along with examining adherence to guidelines for mammography and CBE. Detailed information on study variables is provided in Table 1. Descriptive and logistic regression analyses were conducted using SAS. To avoid over-fitting the regression models, we used $p<0.10$ as the criterion for variable entry. This criterion has been used in previous research on breast cancer screening in women at increased risk for hereditary disease (Isaacs et al., 2002; Lerman et al., 2000). This study was approved by the University of Pennsylvania's IRB.

Table 1
Sample characteristics ($n=65$)[a]

Variable	Level	Total sample n (%)	% Over-adherent BSE[b]	% Adherent mammography[c]
Age	≤50	46 (71)	37	60[d]
	>50	19 (29)	53	95
Marital status	Not married	49 (75)	45	70
	Married	16 (25)	31	91
Education level	≥Some college	48 (74)	35[e]	78
	≤High school	17 (26)	59	67
Employment status	Employed	43 (66)	30[f]	72
	Not employed	22 (34)	64	79
Income[g]	>$35,000	35 (55)	38	82
	≤$35,000	29 (45)	43	67
Health insurance	Yes[h]	61 (94)	41	76
	No	4 (6)	50	67
Family history of cancer	Two or more relatives	56 (86)	43	75
	Less than two relatives	9 (14)	33	75
BRCA1/2 prior probability[i]	≥10%	24 (37)	50	67
	5%	41 (63)	37	79
Breast cancer perceived risk	Much higher/ little higher	46 (71)	33[j]	72
	Much lower/ little lower/ same	19 (29)	63	80

[a] Women were recruited to participate in a study being conducted at the University of Pennsylvania in Philadelphia, PA from February 2003 through December 2005.

[b] Breast Self-Examination (BSE) over-adherence was determined based on the frequency of performing breast self-examination during the past 3 months. Women who examined their breasts four or more times during the past 3 months were categorized as being over-adherent.

[c] Adherence was created based on the last screening date; women who reported having a mammogram during the year prior to the baseline were categorized as being adherent and women who reported that they had never had a mammogram or their last mammogram was obtained more than 1 year before the baseline was categorized as being non-adherent.

[d] Fisher's Exact Test <0.05.

[e] Chi-Square=2.83, $p<0.10$.

[f] Chi-Square=6.69, $p<0.01$.

[g] Income was evaluated by one question that asked women what was their household income before taxes last year: (1) less than $20,000, (2) $20,000–$35,000, (3) $35,001–$50,000, (4) $50,001–$75,000, and (5) greater than $75,000. Income was dichotomized based on the distribution of responses. One participant was missing data for income.

[h] Most women had insurance coverage through an HMO or PPO (69%). Sixteen percent of women had insurance through a fee-for-service program and 14% had Medicare or some other type of insurance coverage.

[i] BRCA1/2=BRCA1/BRCA2.

[j] Chi-Square=5.17, $p<0.02$.

Results

A sizeable minority of women (41%) were over-adherent for BSE (e.g., examined their breasts four or more times, including daily). However, 32% of women were under-adherent (e.g., did not examine their breasts at all or performed BSE only one or two times). Only 26% of women were adherent to BSE recommendations and examined their breasts once per month during the past three months. Among women ages 35 and older ($n=45$), 75% reported having a mammogram during the past year and 93% reported having a CBE. As shown in Table 1, only older age was associated significantly with mammography adherence whereas unemployed women and those with lower perceived risk were most likely to perform excessive BSE. Cancer-specific distress was not associated significantly with mammography adherence (Kruskal–Wallis $\chi^2=0.56$, $p<0.45$) or BSE over-adherence (Kruskal–Wallis $\chi^2=0.56$, $p<0.45$)

Table 2
Logistic regression model of Breast Self-Examination over-adherence [a]

Variable	Level	Odds ratio	95% confidence interval	Number over-adherent	Number under-adherent or adherent
Employment status	Not employed	3.82	1.05, 10.21 [b]	14	8
	Employed			13	30
Education level	≥Some college	0.47	0.14, 1.56	17	31
	≤High school			10	7
Breast cancer perceived risk	Much higher/little higher	0.33	0.10, 1.08 [c]	15	31
	Much lower/ little lower/ same			12	7

[a] Women were recruited to participate in a study being conducted at the University of Pennsylvania in Philadelphia, PA from February 2003 through December 2005. Variables that had a $p<0.10$ association with breast self-examination (BSE) over-adherence (employment status, education, and risk perception) were included in the logistic regression model.
[b] $P=0.04$.
[c] $P=0.07$.

(data not shown). As shown in Table 2, only being unemployed had a significant independent effect on BSE over-adherence. We did not generate a logistic regression model for CBE because more than 90% of women were adherent. Since age was the only variable associated with mammography adherence, we also did not generate a logistic regression model for this outcome.

Discussion

To our knowledge, this is the first empirical study to evaluate breast cancer screening behaviors among African American women at increased risk for hereditary breast cancer recruited from clinical and community settings. Our results suggest that there is a complex pattern of screening in African American women who have a family history of cancer that is suggestive of hereditary breast cancer. In contrast with prior research (Kinney et al., 2002; Isaacs et al., 2002), the majority of women were adherent to mammography and CBE recommendations and older age was positively associated with mammography adherence. We also found that a sizeable minority of women were over-adherent to BSE recommendations. This finding is consistent with BSE practices found in other research with African American women who have a family history of cancer (Hughes et al., 1996). It could be that women examine their breasts frequently because of lack of confidence in mammograms and CBE to detect tumors. Since cancer-specific distress may be elevated among African American women at increased risk for developing breast cancer (Hughes et al., 1996; Halbert et al., 2005b), excessive BSE may be a strategy that women use to cope with their fears about cancer.

In contrast with previous research (Brain et al., 1999), cancer-specific distress was not associated with BSE over-adherence. However, unemployed women were most likely to be over-adherent. Cancer screening is strongly related to health insurance (Rosenberg et al., 2005; Hsia et al., 2000). Since employment is an important predictor of health insurance coverage, it is possible that unemployed women were most likely to be over-adherent because of limited access to mammography and CBE services. However, 94% of women in the present study had health insurance. Previous research has shown that African Americans are more likely than Caucasians to be covered by public insurance programs (Zuvekas and Taliaferro, 2003); women with public insurance may be less likely than women with private coverage to undergo cancer screening (Sung et al., 2002). Thus, even with insurance, other barriers (e.g., lack of transportation) may reduce access to screening among unemployed women and lead to be BSE over-adherence. However, we did not specifically evaluate whether women had public or private insurance coverage; thus, future studies are needed to evaluate the relationship between public versus private insurance coverage and cancer screening behaviors among African American women at increased risk for hereditary cancer.

In considering the results of this study, some limitations should be noted. First, because of the small sample, we had limited power to detect differences in screening practices. Thus, additional research is needed to evaluate screening behaviors in larger samples of African American women who have a family history of cancer that is suggestive of hereditary breast cancer and who are more socioeconomically diverse. An additional limitation may be that we evaluated mammography and CBE among women ages 35 and older, which is younger than the recommended age for these screening tests. However, women at increased risk for developing breast cancer may be advised to consider starting screening earlier (American Cancer Society, 2006). The average age of breast cancer diagnosis of study participant's relatives was 34.7 and the average age at first mammogram was 33.3. Thus, our data are unlikely to be an underestimate of mammography and CBE adherence and provides information on breast cancer screening practices in an understudied group of African American women with a family history of cancer that is suggestive of hereditary disease.

Conclusions

Provision of information about recommendations for cancer surveillance is an important component of genetic counseling for BRCA1/2 mutations. Our results suggest that it may be important to emphasize recommendations for breast cancer screening during genetic counseling to increase adherence. Specifically, since BSE over-adherence may be an indication of cancer-related worry (Brain et al., 1999), attention to these worries may be needed. It may also be important to identify barriers to mammography since a sizeable minority of women were non-adherent. Future studies are needed to evaluate utilization of routine

mammography and changes in breast cancer screening following genetic counseling and testing for BRCA1/2 mutations among African American women.

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Satisfaction with genetic counseling for *BRCA1* and *BRCA2* mutations among African American women

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Abstract

Objective: The objective of this study was to evaluate satisfaction with genetic counseling for *BRCA1* and *BRCA2* (*BRCA1/2*) mutations among African American women.
Methods: Participants were 54 African American women at moderate and high risk for *BRCA1/2* mutations who were offered genetic testing as part of a randomized clinical trial designed to compare the effects of culturally tailored genetic counseling (CTGC) and standard genetic counseling (SGC). Satisfaction with genetic counseling was evaluated using a self-administered questionnaire following culturally tailored or standard pre-test education and counseling.
Results: Overall, the majority of women (96%) were very satisfied with genetic counseling; however, only 26% reported that their worries were lessened and 22% reported that they were able to cope better. Women who received CTGC were significantly more likely than women who received SGC to report that their worries were lessened ($p < 0.05$). In addition, women with household incomes less than US$ 35,000 were significantly more likely to report that the counselor lessened their worries compared to women with higher incomes ($p < 0.05$).
Conclusions: Most African American women were satisfied with genetic counseling; however, women who received culturally tailored genetic counseling were significantly more likely to strongly agree that their worries were lessened compared to women who received standard genetic counseling.
Practice implications: Discussion of cultural beliefs and values during genetic counseling may be beneficial to African American women, especially those with low incomes.

Keywords: African American; Genetic counseling; *BRCA1/2* mutations; Satisfaction

1. Introduction

Recent epidemiological studies have shown that the prevalence of *BRCA1* and *BRCA2* (*BRCA1/2*) mutations ranges between 16% and 21% among African American women who have a personal and family history of breast and ovarian cancer that is suggestive of hereditary disease [1–3]. Women found to carry a risk-conferring *BRCA1/2* mutation have an estimated 55–85% lifetime risk of developing breast cancer and a 15–60% lifetime risk of developing ovarian cancer [4–6]. Previous research has shown that the majority of African American women who are offered participation in genetic counseling and testing choose to participate [7,8]. However, education and counseling for hereditary breast cancer and genetic testing that is not culturally sensitive may

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not be effective for African American women [9]. Hughes et al. [8] found that temporal orientation and religious coping strategies were associated significantly with participating in genetic counseling and testing for *BRCA1/2* mutations among African American women. Based on this research, efforts are now underway to increase the effectiveness of genetic counseling programs targeted to African American women by developing protocols that are sensitive to cultural beliefs and values [10]. Despite this, empirical data from randomized clinical trials are not available on satisfaction with culturally sensitive genetic counseling protocols among African American women.

Patient satisfaction is regarded as a valuable indicator of health care service quality, as it reflects the experience of care from the patients' perspective [11]. With respect to genetic counseling, satisfaction encompasses three dimensions: (1) satisfaction with the professional or technical competence of the health care provider; (2) satisfaction with the counselor's personal qualities or their affective behavior towards the client; (3) satisfaction with administrative procedures such as the cost of counseling and the convenience of obtaining services [12]. Specific aspects of satisfaction with a genetic counselor's technical abilities with respect to his or her counseling skills may include the extent to which individuals believe that the genetic counselor explained things clearly, listened to what they had to say, increased their anxiety, or lessened their worries [12]. Satisfaction has been measured in numerous arenas of genetic counseling, ranging from male infertility [13] to pregnant women's satisfaction with prenatal genetic counseling [14]. Recent studies on satisfaction with genetic counseling for inherited breast–ovarian cancer risk demonstrate that most women are very satisfied with counseling [15–17]. However, African American women are not well represented in these studies. For example, of the 61 women enrolled in the study conducted by DeMarco et al. [15], only 4 were African American women.

We are conducting a prospective randomized clinical trial to compare the effects of culturally tailored genetic counseling (CTCG) and standard genetic counseling (SGC) on decisions about genetic testing, psychological functioning, and health behaviors among African American women at increased risk for hereditary breast–ovarian cancer. Based on prior research showing that standard education and counseling about hereditary breast cancer and genetic testing may not be as effective among African American women relative to white women [9], the CTGC protocol was designed to address cultural factors that have been identified as relevant to health behaviors and clinical genetics among African Americans. For example, Lannin et al. [18] found that religious and spiritual beliefs, such as prayer about cancer can lead to healing, were associated with a greater delay in seeking treatment for breast cancer symptoms. African American women were significantly more likely than Caucasian women to endorse these beliefs [18] and were also more likely to use religious strategies to cope with illness [19]. In other work, high levels of spiritual faith were associated with declining *BRCA1/2* test results in a sample composed of mostly Caucasian women [20], however, African American women who worked with God to consider difficult situations were most likely to participate in genetic counseling and testing for *BRCA1/2* mutations [8]. Other cultural factors (e.g., temporal orientation, communalism) may also be associated with health behaviors among African American women. For example, African American women who had greater levels of communalism were most likely to decline genetic testing [8]. In addition, African American women with a higher present temporal orientation were significantly more likely to have never had a mammogram compared to women with a lower present temporal orientation [21]. Attention to these factors may facilitate the genetic counseling process among African American women; therefore, the CTGC protocol addressed beliefs and values related to: (1) communalism (e.g., the extent to which familial preferences are more important than individual preferences and one's primary duty is to the group or family) [22,23]; (2) spiritual and religious beliefs and coping mechanisms (e.g., one's personal relationship with a higher power and practices and beliefs used to cope with stressful situations) [24,25]; (3) temporal orientation (e.g., one's cognitive focus in terms of past, present, or future domains that individuals use to understand and give meaning to their life experiences) [26–28]. While increased attention to cultural beliefs and values may enhance the sensitivity of genetic counseling, satisfaction with culturally tailored genetic counseling among African American women has not been evaluated. Therefore, the present study compared satisfaction with CTGC versus SGC among African American women at increased risk for hereditary breast–ovarian cancer. Because previous research has shown that exposure to information about genetic testing for inherited disease risk is limited among African American women [29], we were also interested in determining whether expectations about genetic counseling were met among African American women at increased risk for having a *BRCA1/2* mutation. Developing a better understanding of satisfaction with genetic counseling among African American women is needed to develop more effective counseling protocols for this population.

2. Methods

2.1. Study population

This study was conducted at the University of Pennsylvania (Pennsylvania) following approval from the Institutional Review Boards at Pennsylvania and Arcadia University. Participants were African American women at increased risk for having a *BRCA1/2* mutation. To be eligible for participation in the study, women had to self-identify as being African American or Black and be at least 18 years of

age. Women also had to have a minimum 5–10% prior probability of having a *BRCA1/2* mutation based on their personal and family history of breast and/or ovarian cancer to be eligible for participation in the study because this is considered to be the minimum criteria for clinical genetic testing for inherited breast–ovarian cancer risk [30].

2.2. Procedures

Women were recruited to participate in the study through referrals from physicians and clinic staff at the University of Pennsylvania Health System (UPHS). Women were also recruited through referrals from physicians and clinic staff at community hospitals and health clinics located in Philadelphia, PA, as well as African American breast cancer support groups and other community events (e.g., health fairs). Women who were recruited through physicians and clinic staff at the UPHS and other clinical facilities were told about the study during a clinic visit. At health fairs and breast cancer support groups, written information about the study was given to women following a verbal description of the project. Women could also self-refer to the study by responding to newspaper advertisements. Women who were interested in participating in the study completed a referral form in person or by telephone. It should be noted that eleven women were referred to the study by clinic staff while participating in an epidemiological study that was evaluating genetic risk factors for breast cancer among African American women. However, women in the epidemiological study did not receive genetic counseling for *BRCA1/2* mutations or clinical genetic testing for *BRCA1/2* mutations; thus, there was no overlap with the present study. Moreover, participation in the epidemiological study was not associated with enrollment in the genetic counseling study [31]. Racial background, date of birth, and personal and family history of breast and ovarian cancer were collected on the referral form. All referral forms were reviewed by the study genetic counselor (LK) to determine eligibility.

Following referral, eligible women were mailed an introductory letter. The introductory letter described the purpose of the study and the procedures involved in participating. A reply card was also included for women to return if they were not interested in being contacted about study participation. Women who did not decline participation were contacted for a baseline telephone interview about 2 weeks after the introductory letter was mailed. The baseline was a structured survey that assessed sociodemographic characteristics, perceived risk of having a *BRCA1/2* mutation, and interest in genetic testing. This 40-min interview was administered by a professionally trained interviewer from Penn after obtaining verbal consent. At the end of the baseline, women were invited to participate in a genetic counseling research program for African American women. Women who agreed to participate in genetic counseling were randomized to culturally tailored genetic counseling or standard genetic counseling. Detailed information about the counseling protocols is provided below under ‘‘counseling protocols.’’ Written informed consent was obtained for participation in genetic counseling. At the end of the session, all women were offered genetic testing for *BRCA1/2* mutations. All counseling sessions were conducted by a Master’s level, board-certified genetic counselor (LK) who was Caucasian. The study enrollment rate was 62% and of the women who enrolled in the study, 50% participated in genetic counseling [31].

2.3. Counseling protocols

2.3.1. Standard genetic counseling

The standard genetic counseling protocol consisted of education about hereditary breast and ovarian cancer (e.g., *BRCA1/2* susceptibility genes), the process of genetic testing for *BRCA1/2* mutations, and interpretation of genetic test results. Women randomized to the SGC protocol also received information about cancer risks associated with *BRCA1/2* mutations and counseling about their risk of having a *BRCA1/2* mutation based on their personal and family history of cancer. Information about the benefits, limitations, and risks of genetic testing were also provided as a part of the SGC protocol. The SGC sessions lasted about 1.5 h.

2.3.2. Culturally tailored genetic counseling

The culturally tailored genetic counseling protocol provided the same basic education about hereditary breast and ovarian cancer, genetic testing for *BRCA1/2* mutations, and cancer risk information as the SGC protocol. The CTGC protocol differed from SGC in that it included probes that were designed to facilitate discussion about cultural beliefs and values during the counseling process. Consistent with guidelines for culturally competent genetic counseling [32,33], the CTGC protocol incorporated discussion of beliefs and values related to spirituality and religion, temporal orientation, and communalism. The CTGC protocol focused on these cultural beliefs and values based on previous research showing that communalism, spirituality, and flexible temporal orientation are key aspects of an African American cultural worldview [22,23,28,34,35] and our previous research showing that these beliefs and values are associated with decisions about genetic testing among African American women [8].

Specifically, the CTGC protocol included probes that encouraged women to discuss how their cultural beliefs and values are used to make health care decisions and to cope with medical issues. For example, women randomized to the CTGC protocol were asked ‘‘What role does spirituality play in your life and what aspect of your religious and spiritual beliefs would influence your decision to have genetic testing?’’ to address religious and spiritual beliefs and values. Women were also asked ‘‘When you make choices about your healthcare, are you focused on what is going on

now or focused on events that may happen in the future?'' to address values related to temporal orientation. The CTGC protocol also included probes that encouraged women to discuss how concerns about family members may influence their decisions about genetic testing and how relatives may be impacted by their testing decisions (communalism). For example, women were asked to describe how their family experiences with breast and/or ovarian cancer influenced their decisions to have genetic counseling, if they talked to any of their family members about participating in genetic counseling, and how they would feel if their family did not want to them have genetic testing. Discussion of cultural beliefs and values was facilitated by the inclusion of a genogram during the CGTC protocol. The CTGC sessions lasted about 2 h. Detailed counseling notes that documented the issues discussed during each counseling protocol were completed by the genetic counselor following CTGC and SGC. These notes were reviewed by the PI (CHH) to ensure adherence to the counseling protocols. In addition, counseling sessions were randomly audio taped and reviewed by the PI to ensure adherence to the counseling protocols.

2.4. Measures

2.4.1. Sociodemographic characteristics

Age, household income level, marital status, education level, and employment status were obtained during the baseline telephone interview.

2.4.2. Clinical factors

Personal history of breast and/or ovarian cancer and the number of relatives affected with breast and ovarian cancer were obtained at study referral. Prior probability of having a *BRCA1/2* mutation was estimated based on women's personal and family history of cancer using risk estimation models and mutation prevalence tables [3,30,36,37]. Women were categorized as being at moderate risk (5%) or high (10% or greater) risk for having a *BRCA1/2* mutation.

2.4.3. Perceived risk

Perceived risk of having a *BRCA1/2* mutation was evaluated at baseline by one Likert-style item that asked women to indicate how likely it was that they had a mutation (1: not at all likely, 2: somewhat likely, 3: very likely, and 4: definitely). This item has been validated in previous research on interest in genetic testing among Caucasian women [38] and has been used in prior research on education and counseling about hereditary breast cancer and genetic testing among African American women [39].

2.4.4. Satisfaction variables

Satisfaction with the genetic counseling was evaluated using Likert-style items. Specifically, women were asked to indicate how satisfied they were with the genetic counseling session (1: not at all satisfied, 2: a little satisfied, 3: moderately satisfied, and 4: very satisfied). In addition, women were also asked to indicate how much they thought the genetic counselor explained things clearly, listened to what they had to say, used language that they could understand, increased their anxiety, lessened their worries, and helped them to cope better (e.g., helped them to deal with information about their cancer risk) (1: strongly disagree, 2: disagree, 3: agree, and 4: strongly agree). Similar types of items have been used to evaluate overall satisfaction with genetic counseling as well as satisfaction with the counselor's technical ability and affective qualities and the procedural aspects of counseling in previous reports [12,15,16].

We used one Likert-style item to evaluate expectations about genetic counseling. Specifically, women were asked to indicate the extent to which the genetic counseling session met their expectations (1: expectations were exceeded, 2: expectations were met, and 3: expectations were not met). This item has been used in previous research on expectations about genetic counseling [40]. All satisfaction variables were evaluated after the pre-test education and counseling session was completed using a self-administered questionnaire that was given to participants by the genetic counselor.

2.5. Data analysis

Because the sample was small ($n = 54$), our analyses were primarily descriptive. First, we generated frequencies to characterize the study sample in terms of sociodemographic characteristics, clinical factors, and satisfaction variables. We used Fisher's Exact Tests (FET) to compare women at high and moderate risk for having a *BRCA1/2* mutation in terms of sociodemographic factors and *BRCA1/2* perceived risk and to compare women randomized to CTGC and SGC in terms of these variables because of the small sample and cell sizes. We then used FETs to describe the association between counseling group and satisfaction variables. We used this same procedure to describe the association between satisfaction variables and sociodemographic characteristics, clinical factors, *BRCA1/2* perceived risk, and counseling group.

3. Results

3.1. Sample characteristics

Participants were 54 African American women at high and moderate risk for having a *BRCA1/2* mutation. As shown in Table 1, most women were not married (59%), had some college education or were college graduates (76%), were employed (72%), and had an annual household income of US$ 35,000 or more (52%). In terms of clinical characteristics, 69% of women had a personal history of cancer and most (63%) were at high risk for having a

Table 1
Sample characteristics ($n = 54$)

Variable	Level	n (%)
Age (years)	≤50	22 (41)
	>50	32 (59)
Marital status	Not married	22 (41)
	Married	32 (59)
Education level	≥Some college	41 (76)
	≤High school	13 (24)
Employment status	Employed	39 (72)
	Not employed	15 (28)
Income level	>US$ 35,000	26 (49)
	≤US$ 35,000	28 (51)
Cancer history	Affected	38 (70)
	Unaffected	16 (30)
Family history of cancer	Two or more relatives	9 (17)
	Less than two relatives	45 (83)
BRCA1/2 risk level	High	34 (63)
	Moderate	20 (37)

BRCA1/2 mutation. Fifty percent of women had two or more first-degree relatives affected with breast and/or ovarian cancer. The mean (S.D.) age of participants was 46 (12.2). More than 80% of women were referred to the study by physicians and clinic staff. There were no differences in *BRCA1/2* prior probability ($p < 0.78$), cancer status ($p < 0.36$), family history of cancer ($p < 0.29$), marital status ($p < 1.00$), education level ($p < 0.33$), employment status ($p < 1.00$), household income level ($p < 0.78$), or referral source ($p < 0.46$) between women randomized to CTGC or SGC. Women at high and moderate risk for having a *BRCA1/2* mutation did not differ in terms of marital status ($p < 0.09$), income ($p < 0.40$), education ($p < 0.33$), employment ($p < 0.76$), or perceived risk of having a *BRCA1/2* mutation ($p < 0.75$).

3.2. Satisfaction with genetic counseling

Overall, women were very satisfied with the genetic counseling. Ninety-six percent of women reported that they were very satisfied with genetic counseling and 4% reported that they were moderately satisfied with counseling. In addition, the majority of women strongly agreed that the genetic counselor listened to what they had to say (87%), explained things to them clearly (83%), and provided them with new information (61%) (see Fig. 1). While more than half of women reported that the genetic counselor cared for them (57%) and understood their concerns (57%), only 26% of women strongly agreed that their worries were lessened and only 22% strongly agreed that they coped better. Despite this, most women indicated that the genetic counselor did not increase their anxiety (57% strongly disagreed) or confusion (80% strongly disagreed).

Because of the low proportion of women who strongly agreed that their worries were lessened or who strongly agreed that they coped better, we selected these items for further analysis to identify factors that were associated with these satisfaction variables. For these analyses, satisfaction variables were re-coded as ''strongly agree'' versus ''else'' because we were interested in identifying factors that were associated with the highest level of satisfaction with genetic counseling. As shown in Table 2, women who received CTGC were significantly more likely than women who received SGC to report that their worries were lessened ($p < 0.05$). In addition, compared to women who had an annual income of more than US$ 35,000, women with lower incomes were significantly more likely to strongly agree that their worries were lessened ($p < 0.05$). Women with lower incomes and those at moderate risk for having a *BRCA1/2* mutation were also more likely than women with higher incomes and those at high risk to strongly agree that they were able to cope better; however, these associations were only marginally significant. Perceived risk of having a *BRCA1/2* mutation was not associated significantly with either satisfaction outcome (see Table 2). We did not conduct analyses to determine if overall satisfaction with genetic counseling was associated with sociodemographic characteristics and clinical factors or differed between women who received CTGC and SGC because more than 90% of women reported that they were satisfied with genetic counseling overall.

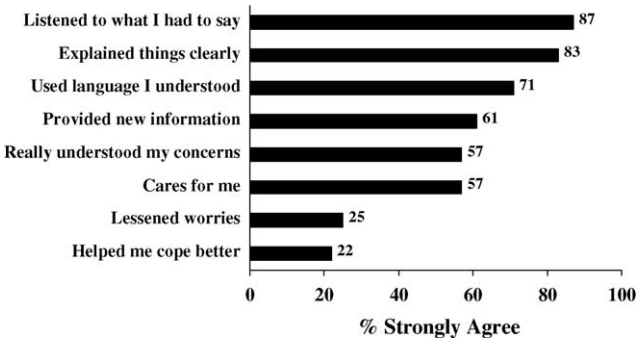

Fig. 1. Satisfaction with genetic counseling.

3.3. Expectations about genetic counseling

Overall, 67% of women reported that their expectations about genetic counseling were exceeded. There were no differences in expectations about genetic counseling between women who received CTGC and SGC. Seventy-one percent of women who received CTGC reported that their expectations were exceeded and 66% of women who received SGC reported that their expectations were exceeded ($p < 0.77$). Expectations about genetic counseling were not associated with *BRCA1/2* prior probability ($p < 0.36$), cancer history ($p < 1.00$), family history of cancer ($p < 0.44$), *BRCA1/2* perceived risk ($p < 0.73$), or sociodemographic characteristics (e.g., marital status, $p < 0.77$; education level, $p < 0.18$).

Table 2
Association between satisfaction and counseling group, sociodemographic characteristics, and clinical factors ($n = 54$)[a]

Variable	Level	Strongly agree (%)	
		Cope better[b]	Lessen worry[b]
Counseling group	CTGC[c]	30	43*
	SGC	19	16
Age (years)	≤50	19	22
	>50	30	33
Marital status	Married	14	18
	Not married	29	32
Education level	≥Some college	20	25
	≤High school	33	31
Employment status	Employed	19	22
	Not employed	27	33
Income level	>US$ 35,000	12†	12*
	<US$ 35,000	32	38
Cancer status	Affected	22	22
	Unaffected	25	38
Family history of cancer	Two or more FDRs[d]	11	33
	Less than two FDRs[d]	26	25
BRCA1/2 prior probability	High	15†	24
	Moderate	37	32
Perceived risk of *BRCA1/2*	Likely	20	22
	Not likely	33	38

[a] Because of the small amount of missing data, not all outcomes have the same sample size indicated above.
[b] Question asked respondents: How much did the genetic counselor help you to cope better or lessen your worries.
[c] CTGC: culturally tailored genetic counseling; SGC: standard genetic counseling.
[d] FDR: first-degree relatives.
* $p < 0.05$.
† $p < 0.10$.

4. Discussion and conclusion

4.1. Discussion

To our knowledge, this is the first empirical study to evaluate satisfaction with genetic counseling for *BRCA1/2* mutations among African American women at increased risk for hereditary breast and ovarian cancer. Overall, the majority of women were very satisfied with genetic counseling. These results are consistent with findings reported in prior studies of patient satisfaction with genetic counseling [15,17,41,42] and research on the role of expectancy violations theory in genetic counseling [40]. One possible explanation for the high levels of satisfaction found in this study is that women were not sure what to expect from genetic counseling. Previous research has shown that after adjusting for education level, awareness about genetic testing and knowledge about breast cancer genetics are limited among African American women [29,43,44]. However, more than 60% of women in the present study reported that their expectations about genetic counseling were exceeded. A recent study also found that among African American women who had heard about genetic testing, concern about some of potential limitations and risks of genetic testing are high [43] even though women may have favorable attitudes about the benefits of genetic testing [29,45]. It is possible that women initially had mixed feelings about testing, but their expectations were exceeded following a discussion about hereditary breast cancer and genetic testing and provision of cancer risk information. However, we did not evaluate expectations about genetic counseling prior to the pre-test education and counseling session; thus, future studies are needed to evaluate expectations about genetic counseling among African American women before counseling is provided.

Although expectations about genetic counseling were exceeded for the majority of women and most participants were satisfied with genetic counseling overall, satisfaction with all aspects of counseling was not uniformly high. Only about one-fourth of women strongly agreed that their worries were lessened and that they were able to cope better. It is possible that worries were not lessened because women were provided with new information about cancer risks for themselves and their family members. Interestingly, women who received culturally tailored genetic counseling were significantly more likely than women who received standard genetic counseling to report that their

worries were lessened. Women who received culturally tailored genetic counseling may have been more satisfied because the CTGC protocol included a discussion of spiritual and religious beliefs and practices that they use to make health care decisions and to cope with medical issues. Discussion of the potential impact of genetic testing on family members during culturally tailored genetic counseling, and how they would cope with these reactions, with the genetic counselor may have also lessened worry among women who received this protocol.

We also found that women with lower incomes were significantly more likely than women with higher incomes to strongly agree that their worries were lessened. Women with low incomes may have fewer resources for health information; it is likely that information about hereditary breast cancer, genetic testing, and risk of having a *BRCA1/2* mutation provided by the genetic counselor reduced worries among these women. Another possible explanation is that women with low incomes may have a tendency to give socially desirable responses to questions that evaluate the satisfaction with sources for health information that may not be readily accessible. However, previous research has shown that low income is positively associated with greater distress among African Americans in the general population [46,47] and African American breast cancer survivors [48]. Other work has shown that African American women with low incomes are most likely to experience reductions in psychological distress following a psychoeducational intervention [49]. Our recent study found that African American women at high and moderate risk for having a *BRCA1/2* mutation report elevated levels of cancer-specific distress [50]; thus, additional research is needed to evaluate the association between income level and psychological functioning following genetic counseling for inherited breast–ovarian cancer risk among African American women.

In considering the results of this study, several limitations should be noted. First, the small sample size prevented us from conducting multivariate analyses to evaluate the independent effects of sociodemographic characteristics, clinical factors, and counseling group on satisfaction variables. However, the challenges associated with recruiting African Americans to participate in genetic counseling and testing for hereditary cancer have been described in previous reports [51]; to our knowledge, the present report is the first to evaluate satisfaction with genetic counseling among African American women at increased risk for having a *BRCA1/2* mutation. It is important to note that the majority of African American women recruited to participate in this study enrolled in the research and completed genetic counseling [31]. Although similar types of items and data collection procedures have been used to evaluate satisfaction with genetic counseling in prior reports [12,15,16], the single items that we used to measure satisfaction and the methods used to collect these data (e.g., self-administered questionnaires distributed by the genetic counselor) may have increased the potential for socially desirable responses. Since we did not evaluate expectations about genetic counseling prior to the counseling sessions, it was not possible to determine how these expectations may have changed. Thus, future studies are needed to evaluate pre- and post-counseling expectations about genetic counseling and satisfaction among larger samples of African American women at increased risk for hereditary breast cancer. Within these studies, it will be important to determine the specific ways in which worry may change following genetic counseling (e.g., worry about one's cancer risk or worry about one's family members) and the impact of these changes on health behaviors and communication with family members about genetic testing among African American women. Studies are also needed to evaluate the long-term effects of genetic counseling on psychological functioning among African American women using standardized measures of general and cancer-specific distress and how satisfaction, including changes in worry immediately following genetic counseling, may correspond to post-counseling psychological functioning in this population. Another potential limitation is that while our sample was similar to Philadelphia residents in the 2000 Census in terms of marital status, our study sample may have had greater education and household incomes. However, prior reports have shown that most women who participate in genetic counseling and testing for *BRCA1/2* mutations are employed and have some college education [20,52]. Thus, our sample is likely to be similar to women from other racial groups who participate in genetic counseling and testing in terms of sociodemographic characteristics. Another potential limitation is that counseling was provided by one Caucasian genetic counselor. However, the genetic counseling profession is composed primarily of Caucasian women and provision of culturally tailored and standard genetic counseling by a Caucasian genetic counselor is likely to enhance the generalizability of the counseling protocols.

4.2. Conclusions

The results of this study demonstrate that African American women recruited to participate in genetic counseling research are satisfied with counseling for *BRCA1/2* mutations. However, satisfaction with some aspects of genetic counseling may vary depending on women's income level and the type of counseling provided. Women who received culturally tailored genetic counseling were significantly more likely to strongly agree that their worries were lessened compared to women who received standard genetic counseling. The results from this study provide novel, preliminary information on satisfaction with genetic counseling for *BRCA1/2* mutations among African American women that have important implications for how genetic counseling for *BRCA1/2* mutations is provided to this population.

4.3. Practice implications

Increasingly, efforts are being directed towards enhancing access to genetic counseling and testing for inherited breast–ovarian cancer risk among African American women. Previous research has shown that culturally sensitive educational materials may improve comprehension of complex medical information among ethnic and racial minorities [53–55]. Our results suggests suggest that discussion of cultural beliefs and values during genetic counseling for *BRCA1/2* mutations may be effective for African American women, especially those with low incomes. Discussion of cultural beliefs and values related to spiritual and religion, family relationships, and temporal orientation may be one way to facilitate genetic counseling among African American women at increased risk for hereditary breast cancer. Additional research is needed to evaluate the effects of culturally tailored genetic counseling on decisions about genetic testing and psychosocial and behavioral outcomes among this population.

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